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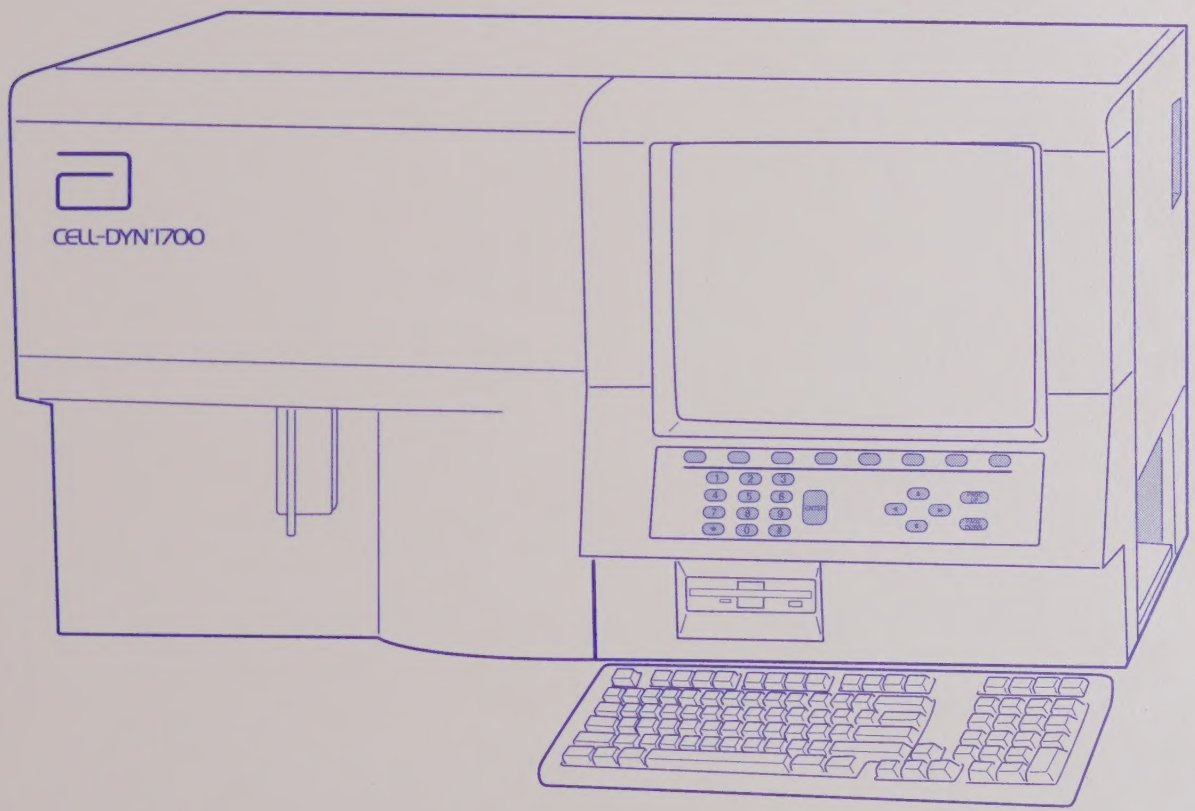
CELL-DYN® 1700 SYSTEM



Operations Manual

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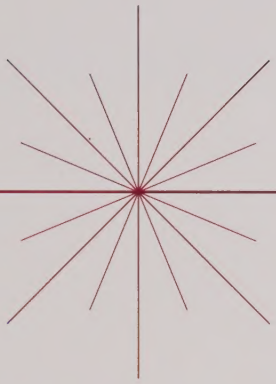

ABBOTT

CELL-DYN® 1700 SYSTEM

Operations Manual

List Number 03H58-01

Abbott Laboratories
Abbott Park, IL 60064
9230713A - February 1995

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Foreword

Congratulations on becoming a proud operator of the CELL-DYN® 1700 System. Using state-of-the-art technology, we have designed your instrument to function consistently and dependably on a day-to-day basis.

The CELL-DYN 1700 System is backed by dedicated professionals who excel in engineering, training, and technical expertise. As you are a valued customer, we will teach you how to operate, maintain, and troubleshoot your system.

For continuing service, we also provide telephone technical assistance should you need additional information or assistance in diagnosing a problem. This service is available 7 days a week, 24 hours a day in the United States.

If a problem should arise that cannot be resolved by telephone, on-site support is offered by Abbott's Field Service Representatives. Our Field Service Representatives are extensively trained in all aspects of Abbott instrumentation, which assures proficiency in diagnosing, isolating, and correcting problems.

Abbott Laboratories is dedicated to manufacturing the highest quality, most reliable instrumentation available. We look forward to serving your needs in any way possible.

Customer Support

United States: 1 (800) CELL DYN or 1 (800) 235-5396

Abbott Diagnostics Customer Support Center:
5440 Patrick Henry Drive
Santa Clara, CA 95054

Canada: 1 (800) 387-8378

International: Call your local customer support representative.

Intended Use

The CELL-DYN 1700 is a multiparameter hematology analyzer designed for *in vitro* diagnostic use in clinical laboratories as well as physician office laboratories.

Proprietary Statement

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Patent Statement

The CELL-DYN® 1700 System, including reagents, may be covered by one or more of the following U.S. Patents: 4,710,021; and 5,227,304. Other patents may be pending.

Instrument Disclaimer

All operating instructions must be followed. In no event shall Abbott be responsible for failures, errors, or other liabilities resulting from a customer's noncompliance with the procedures and precautions outlined herein.

Pictorial Disclaimer

The sample printouts/screens contained in this manual are for information and illustration purposes only. Abbott Laboratories makes no representations or warranties about the accuracy and reliability of the information on the printouts/screens, and this information is not to be used for clinical or maintenance evaluation.

Abbott Instrument Warranty

Abbott Laboratories warrants CELL-DYN Instruments sold by Abbott Sales Representatives (the "Instrument") to be free from defects in workmanship and materials during normal use by the original purchaser. This warranty shall continue for a period of one (1) year, commencing twenty-one (21) days from date of shipment to the original purchaser, or until title is transferred from the original purchaser, whichever occurs first (the "Warranty Period").

If any defects occur during the Warranty Period, contact your Abbott Customer Support Center immediately and be prepared to furnish pertinent details concerning the defect, the Instrument model number, and the serial number.

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2. Field Service Representative support: 8:30 A.M. to 5:00 P.M. Monday through Friday (excluding all Abbott-observed holidays).
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2. Result from chemical decomposition or corrosion.
3. Are caused by customer or third party abuse, misuse, or negligence, or by failure to comply with any requirement or instruction contained in the applicable Abbott Operations Manual.
4. Result from maintenance, repair, or modification performed without Abbott's authorization.

Abbott's liability for all matters arising from the supply, installation, use, repair, and maintenance of the Instrument, whether arising under this Warranty or otherwise, shall be limited solely to the repair or (at Abbott's sole discretion) replacement of the Instrument or of components thereof. In no event shall Abbott be liable for injuries sustained by third parties, incidental or consequential damages, or lost profits. Replaced parts shall become the property of Abbott Laboratories.

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The CELL-DYN 1700 Series Hematology Systems are manufactured by Abbott Diagnostics, a wholly owned subsidiary of Abbott Laboratories, at 5440 Patrick Henry Drive, Santa Clara, CA 95054, U.S.A. Please direct all inquiries concerning information in this manual to the foregoing address.

NOTE: Direct all inquiries regarding equipment problems to the Abbott Customer Support Center. (U.S. customers only.)

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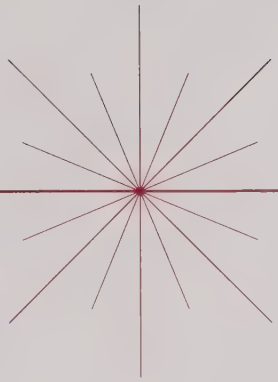

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CELL-DYN® 1700 SYSTEM

How To Use This Manual

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How to Use This Manual

Overview

This Operations Manual contains complete instructions for using and maintaining the CELL-DYN® 1700 System.

This manual was designed to fill several needs, from providing step-by-step operating instructions to listing accessory part numbers. You will find it a valuable aid as you learn to use the system and an essential reference thereafter.

A basic principle of effective learning is to proceed from the general to the specific. That is the way the material in this manual is presented. And that is how we wish to present the manual to you.

The first and most important step is to get acquainted with the ***Master Table of Contents***. For this reason, we start with a brief overview to show you how the information is organized in sections.

After that, we explain how the manual is physically designed to help you locate desired information quickly and easily.

Finally, we discuss different ways material is presented for different purposes and explain various icons that identify specialized types of information in the text.

Please take the time to read and understand this brief preparatory section.

Manual Organization

Front Matter
The pages in front of the ***Master Table of Contents*** contain a Foreword that includes customer support and intended use information. These pages also contain proprietary, warranty, and trademark statements.

Section 1. ***Use or Function***
This section provides an overall description of the system and its components. It names the major system components and tells what they are used for.

Section 2. ***Installation Procedures and Special Requirements***
This section provides detailed instructions for system setup and configuration. It explains proper location, installation, setup, and configuration to meet your laboratory's specific needs.

Section 3. ***Principles of Operation***
This section explains the principles behind the system's operation. It describes what the system measures and how those measurements are made. It also explains the translation of those measurements into useful data and reports for the user.

Section 4. ***Performance Characteristics and Specifications***
This section contains useful details on the dimensions of the instrument, proper operating environment, and performance specifications.

Section 5. ***Operating Instructions***
This section explains the procedures for daily start-up and shutdown, sample collection and handling, routine operation of the instrument, sample analysis, and use of the data log.

Section 6. ***Calibration Procedures***
This section takes you step by step through the calibration process. It discusses calibration materials, guidelines, and methods, including troubleshooting procedures and corrective action.

Section 7. ***Operational Precautions and Limitations***
This section contains a summary of known factors that may adversely affect the proper operation of the instrument or the quality of the output.

Section 8. ***Hazards***
This section covers possible hazards arising from the operation of the instrument, as well as decontamination and waste handling procedures.

Section 9. ***Service and Maintenance***
This section discusses routine maintenance and cleaning on a daily, weekly, monthly, and "as needed" basis. Also included are detailed instructions for removing, cleaning, and replacing various components to ensure proper system performance.

Section 10. ***Troubleshooting and Diagnostics***
This section discusses the diagnostics capability of the instrument. It contains a troubleshooting guide to help users identify probable causes of a system malfunction or of suspect data, and to suggest the proper corrective action.

Section 11. ***Quality Control***
This section covers the proper mixing, handling, and running of control material, setting up QC files and using the QC capabilities of the instrument, and setting up and using the X-B Analysis Program. It also provides a review of the Westgard Rules.

Section 12. ***Printers***
This section reviews the setup and use of printers for graphics output and ticket printing.

Section 13. ***CELL-DYN 1700CS — Closed Sample Aspiration***
This section includes material from all the previous sections which pertains specifically to the installation, operation, and maintenance of the Closed Sample instrument, such as calibrating the Closed Mode and cleaning the Tube Holder Well and Cap Piercing Needle.

Bibliography
This section contains a listing of reference sources for the user who wishes more background information about the system or a topic discussed in this manual.

Revision Status and Log
This section is a regulatory requirement and is maintained by the system administrator.

Glossary
This section contains the words and terms used in hematology as they apply to the CELL-DYN 1700 System, as well as terms that describe the actual operation, principles of operation, and components of the system.

Appendices

Appendix A lists the part numbers of components, accessories, controls, reagents, and consumables associated with the CELL-DYN 1700 System for user convenience when placing orders.

Appendix B contains two tables, which provide users with further insight into the operation of the system: Table B-1, Potential Causes of Spurious Results with Automated Cell Counters, and Table B-2, Reference Intervals (Normal Values) for Automated Blood Counters.

Index
This section contains an alphabetical listing of subject matter to help users quickly locate specific information about the system.

Manual Construction

The physical construction of the manual supports its sectional organization.

Master Table of Contents
The Master Table of Contents at the beginning of this manual lists each section and its subsections.

Section Separators and Tables of Contents
A large separator tab marks the start of each section. A section table of contents is located immediately behind this tab in most sections.

Text Conventions Used in This Manual

The following list summarizes the text conventions that are used in this manual:

Information	Presentation	Examples
Menu name	Sans serif font, all capital letters, bold	MAIN MENU DATA LOG menu
Soft keys (screen label keys)	Sans serif font, all capital letters, bold, enclosed in brackets	[RUN]
Keyboard/keypad keys	Regular font, initial capital letters only when appropriate	arrow keys ↑ arrow key Enter key ESC key Page Up key the pound (#) key the asterisk (*) key
Status	Sans serif font, all capital letters	READY STANDBY INITIALIZED
Data entry field	Sans serif font, bold, enclosed in angle brackets	<OPERATOR ID> field
Screen message or other screen display	Sans serif font, bold	Waste Full
ON and OFF	All caps, regular font	ON OFF

Soft Keys (Screen Label Keys)

Screen labels are menu keys displayed at the bottom of the display screen. Directly below the display screen is a row of eight unlabeled pressure-sensitive keys which correspond to the menu labels. Pressing one of these keys (on the membrane keypad) initiates the action specified by the corresponding menu label.

This manual indicates that one of these "soft keys" is to be pressed by showing the label in all caps, bold, sans serif font, and enclosed in brackets. For example, when the manual calls for the operator to press the key under the RUN label and then the key under the SPECIMEN TYPE label, the text will read "Press **[RUN]** followed by **[SPECIMEN TYPE]**."

Keyboard/Keypad Keys

In some cases, the operator must press a key on the PC keyboard or on the pressure-sensitive keypad on the front of the instrument. Such keys include the Enter key, the ESC key, the pound (#) key, and other special function keys. Special function keys, such as the arrow keys, are in regular type. The arrow symbol may be substituted for the word. For example, the text will read "Press the arrow keys" or "Press the ↑ key" or "Press the ↑ arrow key."

Graphic Conventions Used in This Manual

Throughout the text, signal words and icons appear where the nature of the information warrants special attention.

> NOTE: The *note* signal word appears adjacent to an important point of information that is relevant to the current subject matter.

This manual uses four icons to warn users of possible danger. These icons are:

WARNING: Potential Biohazard. The biohazard icon alerts users to an activity or area where they may be exposed to infectious materials or substances.

WARNING: Electrical Shock Hazard. The electrical warning icon alerts users to the possibility of electrical shock in the described activity or at the posted location.

WARNING: The general warning icon alerts users to a potential health or safety hazard.

CAUTION: The general caution icon appears adjacent to an explanation of conditions that could interfere with the proper functioning of the instrument.

Conclusion

We hope you have found this preview of the manual useful. The information in this section should help you better understand the construction and organization of this manual and help you get started easily and quickly.

NOTES

ABBOTT

CELL-DYN® 1700 SYSTEM

Use or Function

Use or Function
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NOTES

Overview

The CELL-DYN® 1700 System is a multiparameter hematology analyzer designed for *in vitro* diagnostic use in clinical laboratories as well as physician office laboratories. The instrument has two models: the CELL-DYN 1700 and the CELL-DYN 1700CS. The CELL-DYN 1700 model accepts specimens from open collection tubes containing undiluted whole blood (referred to as Open Sample Mode) and from pre-diluted samples (Pre-Dilute Mode). The CELL-DYN 1700CS model accepts specimens from closed collection tubes (Closed Sample Mode) in addition to the two modes mentioned above.

The CELL-DYN 1700CS System is equipped with an attached Closed Sample Aspiration Assembly. The Closed Sample model aspirates blood from a closed collection tube that has been inserted in the Closed Sample Aspiration Assembly. A description of the CELL-DYN 1700CS, including installation, operating, and maintenance instructions, and drawings, is found in **Section 13: *CELL-DYN 1700CS — Closed Sample Aspiration.***

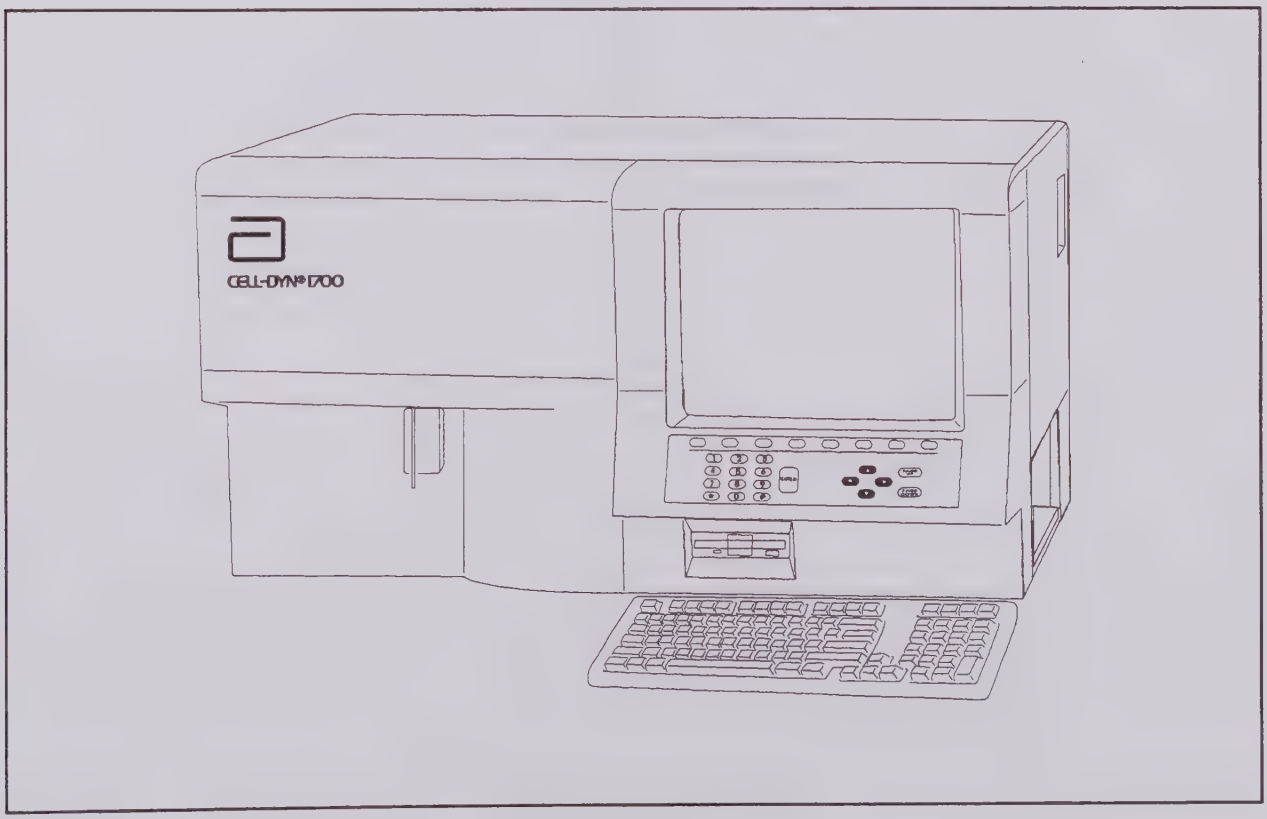


Figure 1.1: The CELL-DYN® 1700 System

Parameters Measured

The CELL-DYN 1700 generates the following measurements on Tri-potassium EDTA (K3 EDTA) anticoagulated whole blood:

- WBC — white blood cell or leukocyte count
- RBC — red blood cell or erythrocyte count
- HGB — hemoglobin concentration
- PLT — platelet or thrombocyte count
- LYM — lymphocyte absolute count
- %LYM — lymphocyte percent
- GRAN — granulocyte absolute count
- %GRAN — granulocyte percent
- MID — mid-range absolute count
- %MID — mid-range percent
- MCV — mean red cell volume
- HCT — hematocrit
- MCH — mean red cell hemoglobin
- MCHC — mean red cell hemoglobin concentration
- RDW — red cell distribution width
- MPV — mean platelet volume
- PCT* — plateletcrit
- PDW* — platelet distribution width

*Clinical significance has not been established for these parameters. Therefore, they are not reportable.

System Components

The CELL-DYN 1700 Instrument is a single unit that includes a Specimen Analyzer and a Data Module. Printers, which are a separate component, are described in **Section 12: *Printers.***

Analyzer

The Analyzer section contains the hardware to aspirate, dilute, and analyze each whole blood specimen. The Analyzer contains the following major components accessible by users:

- Front Panel
- Flow Panel
- Left Side Panel
- Right Side Panel
- Rear Panel

Front Panel

The components visible on the front of the Analyzer are identified in the following figure. The functional description of each component follows.

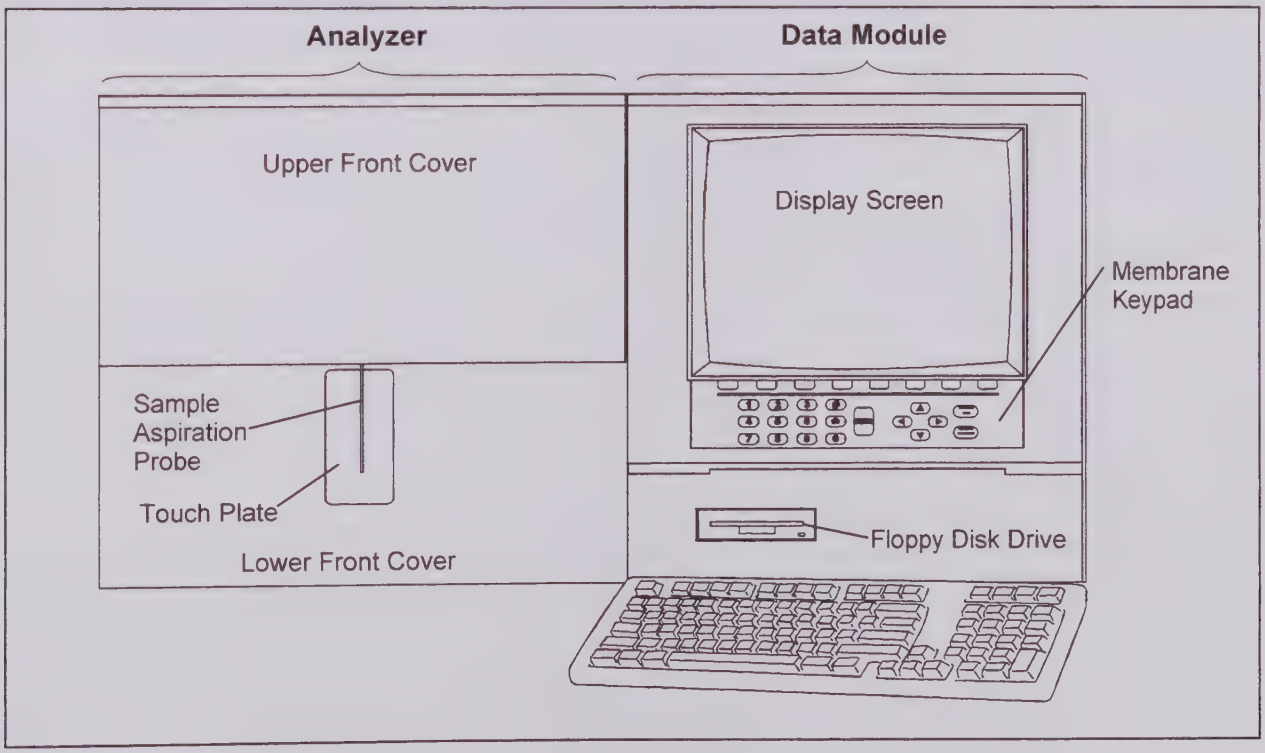


Figure 1.2: Front Panel

Upper Front Cover

The Upper Front Cover protects the upper Flow Panel. A green Ground Wire provides electrical continuity for shielding purposes. Access to the upper Flow Panel is necessary to completely view the operation of the Upper Flow Panel components and to perform certain maintenance operations.

Lower Front Cover

The Lower Front Cover protects the lower section of the Flow Panel. Access to the lower Flow Panel is necessary to view the action of the lower Flow Panel components and to perform certain maintenance procedures. Always leave the Lower Front Cover on during equipment operation to reduce the electronic noise level.

Sample Aspiration Probe

The Sample Aspiration Probe is used to aspirate whole blood from an opened collection tube. After each aspiration, waste liquid on the outside of the probe is removed as the probe is drawn through the Wash Block.

Touch Plate

The Touch Plate is a spring plate located directly behind the Sample Aspiration Probe. Pressing the Touch Plate starts the selected run cycle.

Flow Panel

The Flow Panel is located behind the Upper and Lower Front Covers. The major components of the Flow Panel are depicted in the following figure. The functional description of each component follows.

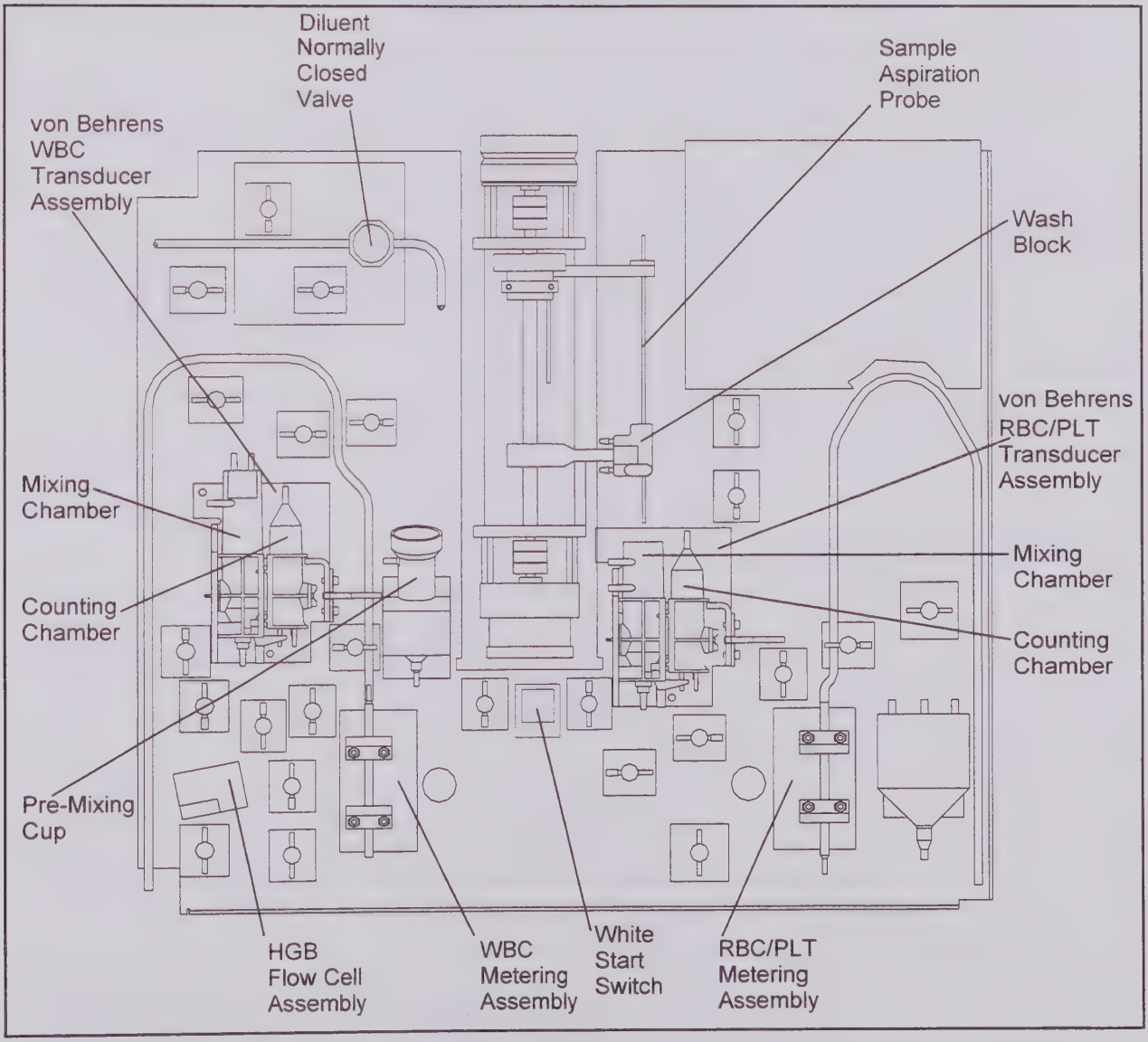


Figure 1.3: **Flow Panel — Open Mode View**

Sample Aspiration Probe

The Sample Aspiration Probe aspirates the blood sample from an open VACUTAINER® tube and delivers the sample to the Pre-Mixing Cup for the first dilution process. The probe then aspirates the diluted solution from the Pre-Mixing Cup and delivers the solution to the RBC/PLT Mixing Chamber for the second dilution process.

Wash Block

The Wash Block rinses the outside of the Sample Aspiration Probe with diluent. Excess diluent is routed to the waste container.

RBC/PLT Metering Assembly

The RBC/PLT Metering Assembly contains a precision-bore glass tube with a set of optical detectors, one upper and one lower, mounted on it. It is used to meter a fixed volume of the RBC/PLT dilution during the RBC/PLT measurement portion of each cycle.

von Behrens RBC/PLT Transducer Assembly

The von Behrens RBC/PLT Transducer Assembly contains the fluidics and hardware required for accurate measurement of the diluted red blood cells and platelets. The primary components of this assembly are:

- The RBC/PLT Transducer — The transducer contains two chambers. The Mixing Chamber on the left is used to mix the RBC/PLT dilution. The Counting Chamber on the right contains the divider plate used to prevent cells that have traversed the aperture from recirculating into the sensing zone.
- Electrodes — There are two noncorrosive, electrically conductive plates, one positively charged and one negatively charged. One electrode is located in each transducer chamber. The electrodes conduct a constant current flow through the aperture during the RBC/PLT measurement portion of each cycle.
- RBC/PLT Aperture Plate — This plate is inserted into a slot between the two transducer chambers. A jewel containing the aperture is heat-embedded into the plate.

WBC Metering Assembly

The WBC Metering Assembly contains a precision-bore glass tube with a set of optical detectors, one upper and one lower, mounted on it. It is used to meter a fixed volume of WBC/HGB dilution during the WBC measurement portion of each cycle.

von Behrens WBC Transducer Assembly

The von Behrens WBC Transducer Assembly contains the fluidics and hardware required for accurate measurement of the diluted white blood cells. The primary components of this assembly are:

- WBC Transducer — The transducer contains two chambers. The Mixing Chamber on the left is used to mix the WBC/HGB dilution. The Counting Chamber on the right contains the divider plate used to prevent cells that have traversed the aperture from recirculating into the sensing zone.
- Electrodes — There are two noncorrosive, electrically conductive plates, one positively charged and one negatively charged. One electrode is located in each transducer chamber. The electrodes conduct a constant current flow through the aperture during the WBC measurement portion of each cycle.
- WBC Aperture Plate — This plate is inserted into a slot between the two transducer chambers. A jewel containing the aperture is heat embedded into the plate.

HGB Flow Cell Assembly

The HGB Flow Cell Assembly contains the following components:

- A fully enclosed (light-tight), flow-through glass cuvette
- An LED light source
- An interference filter used to obtain the ICSH (International Committee for Standardization in Hematology) recommended wavelength of 540 nm (nanometers)
- A photodetector for measuring the light transmitted

Diluent Normally Closed Valve

The Diluent Normally Closed Valve on the Flow Panel prevents diluent from escaping through the Wash Block in the event of a sudden power shutoff.

Left Side Panel

The components on the lower Left Side Panel of the instrument are depicted in the following figure. The functional description of each component follows.

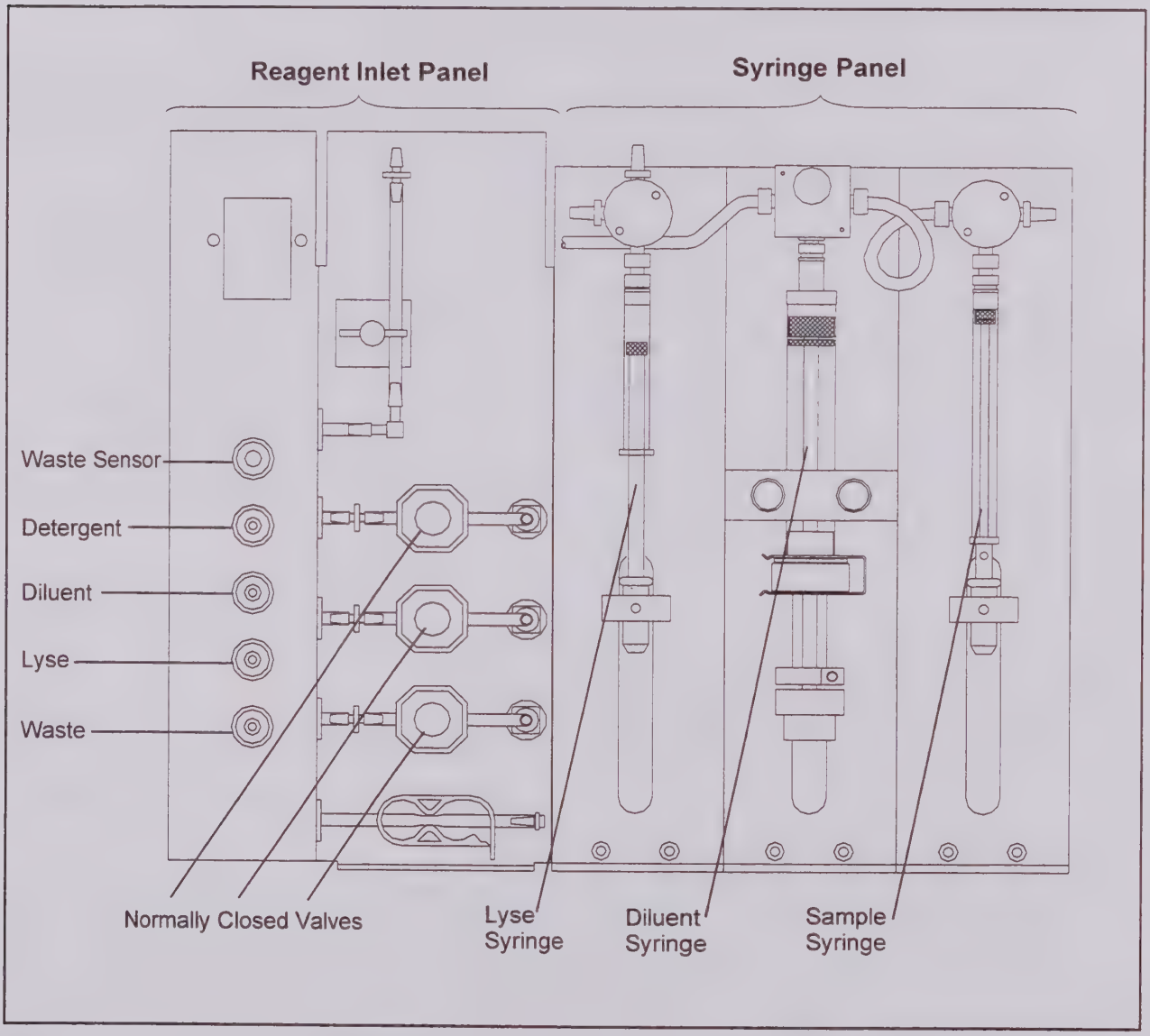


Figure 1.4: Lower Left Side Panel

Waste Sensor Connector

The Waste-Full Sensor Plug connects to the Waste Sensor Connector Port. When the electrical sensor is tripped, the **Waste-Full** message is generated and the READY status is inhibited until the situation is corrected. The System interprets a disconnected plug the same way as a full waste container. Therefore, if the waste is routed to a drain, a dummy plug must be inserted in the connector.

Detergent Inlet Tubing Connector

This color-coded (green) port is used to connect the Detergent Inlet Tubing with its associated cap, weighted end, and label.

Diluent Inlet Tubing Connector

This color-coded (red) port is used to connect the Diluent Inlet Tubing with its associated cap, weighted end, and label.

HGB Lyse Inlet Tubing Connector

This color-coded (blue) port is used to connect the WBC/HGB Lyse Inlet Tubing with its associated cap, weighted end, and label.

Waste Outlet Tubing Connector

This color-coded (black) port is used to connect the Waste Outlet Tubing.

Normally Closed Valves

The three Normally Closed Valves prevent the detergent, diluent, and lyse from draining back into the reagent containers when the instrument power is turned OFF.

Syringes

The instrument contains three syringes: Lyse, Diluent, and Sample.

- The Lyse Syringe delivers a specific volume of lyse to the WBC Mixing Chamber for the white cell count and hemoglobin measurement.
- The Diluent Syringe delivers a specific volume of diluent to dilute the blood in the mixing chambers.
- The Sample Syringe aspirates and dispenses a specific volume of sample.

Rear Panel

The components visible on the Rear Panel of the instrument are depicted in the following figure. The functional description of each component follows.

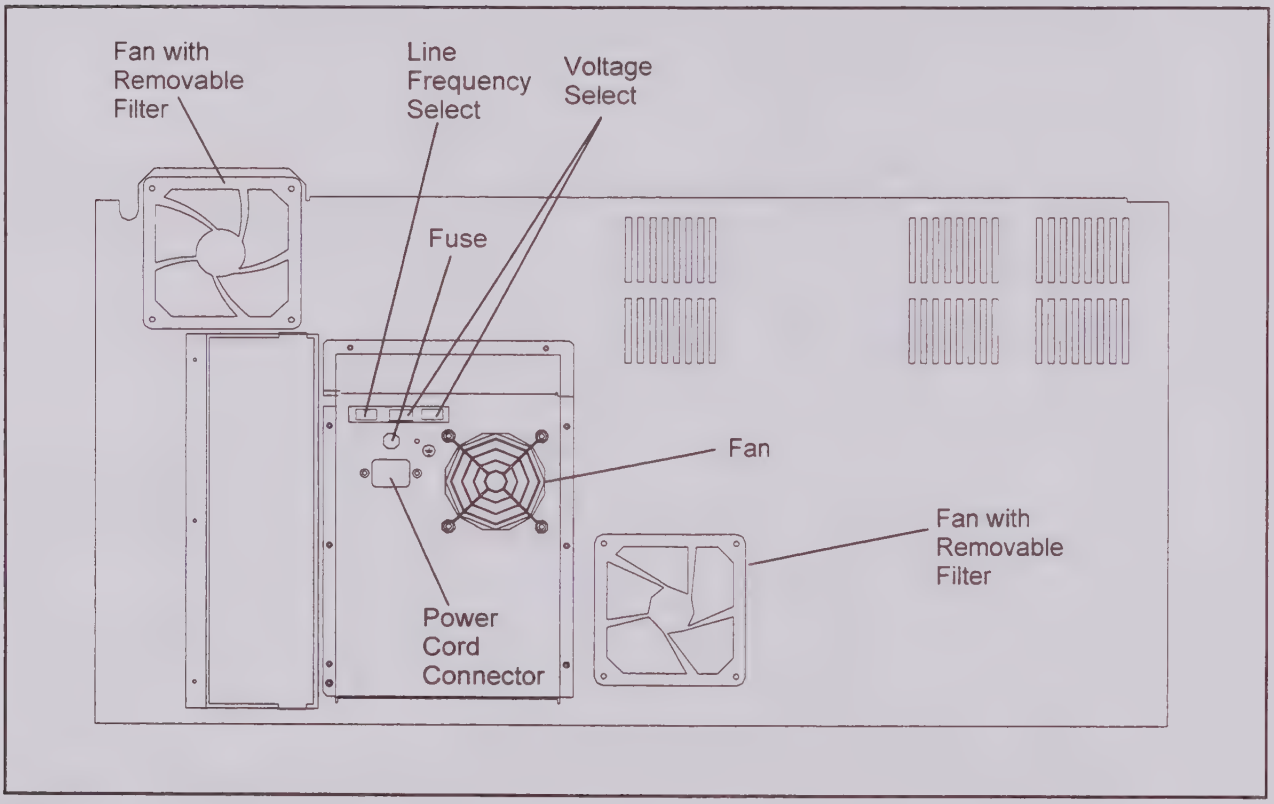


Figure 1.5: Rear Panel

Line Frequency Select

This switch is used to select either 50 or 60 hertz operating frequency.

Voltage Select

This switch is used to select a 100, 120, 220, or 240 volt power setting.

Fans

Air Intake Fans cool the internal components of the instrument. They are covered with filters that are easily removed, as required, for routine cleaning.

Fuse

The fuse is located directly above the Power Cord Connector. The CELL-DYN 1700 System uses two types of fuses: a 5-amp slow-blow fuse for 110/120 VAC operation and a 2.5-amp slow-blow fuse for 220/240 VAC operation. Be sure to use the correct fuse for the designated power setting. (The Accessory Kit contains both fuse types.)

Power Cord Connector

This receptacle is used to connect the Main Power Cord to the instrument.

Right Side Panel

The components visible on the Right Side Panel of the instrument are depicted in the following figure. The functional description of each component follows.

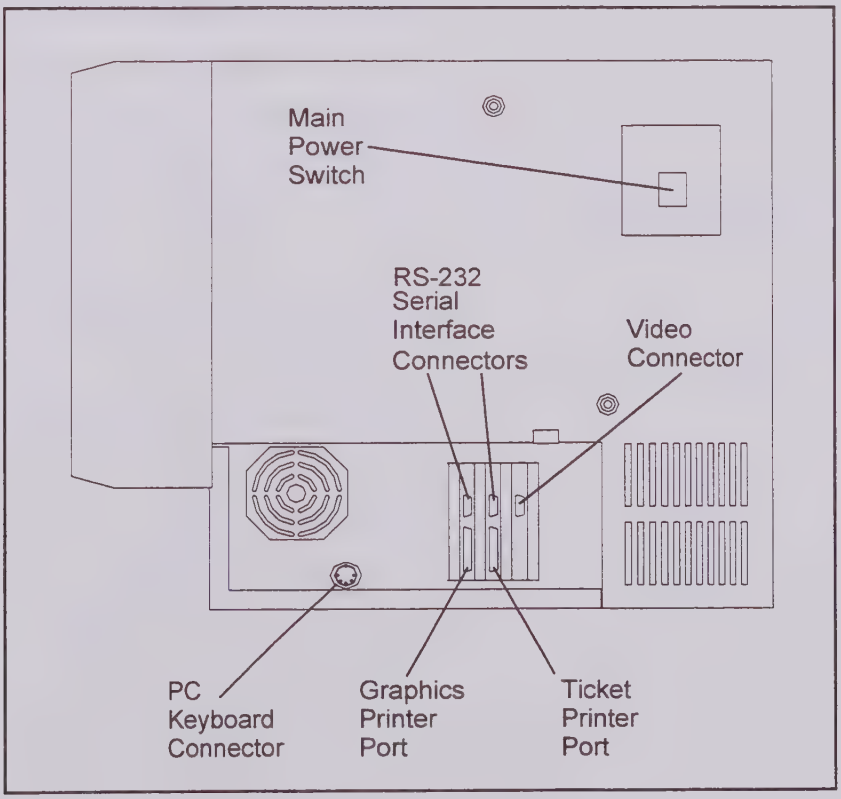


Figure 1.6: Right Side Panel

Main Power Switch

This is the main power switch for the instrument.

Video Connector

This port is used to connect the built-in monitor to the instrument.

PC Keyboard Connector

This port is used to connect the PC Keyboard to the instrument.

RS-232 Serial Interface Connectors (2)

These ports are used to connect a serial 9-pin connector to an optional external device that accepts serial data in ASCII format.

Parallel Interface Connector (Graphics Printer Port)

This port is used to connect the 25-pin Printer Cable from the printer supplied with the instrument.

Parallel Interface Connector (Ticket Printer Port)

This port is used to connect a 25-pin Printer Cable to the optional printer used to print data in a ticket format.

Data Module

The Data Module section includes the Computer, Video Display Monitor, Membrane Keypad, PC Keyboard, Hard Disk Drive, and Floppy Disk Drive.

CELL-DYN 1700 operations are controlled by high-speed microprocessors that monitor system status, perform the various analytical routines used by the instrument, perform diagnostic checks, and store result data.

Serial data (ASCII format) may be transferred to an external computer through an RS-232 connector on the Right Side Panel. Data transmission may be done either automatically as samples are processed or by command of the operator. Data may be output to an on-line printer through the Parallel Interface Connectors.

Data Storage

Hard Disk Drive

A Hard Disk Drive is used to store the User Interface Software and Patient Data Log. It has sufficient capacity to store 5000 samples, including numeric and graphics data.

Floppy Disk Drive

A 1.44 Megabyte 3.5" Floppy Disk Drive is used to load assay values and download Quality Control (QC) files.

Video Display Monitor

A 14-inch diagonal color Video Display Monitor displays all alphanumeric and graphics data. It has a high-resolution 16-color capability. There are five adjustment controls located behind the Membrane Keypad and under the Display Screen. The controls from left to right are: contrast, brightness, height, horizontal position, and width.

Membrane Keypad

A row of eight unlabeled pressure-sensitive keys is located directly below the screen. An audible tone is generated when each key is pressed. Each key initiates a function defined by the screen label currently displayed directly above it. These keys are also called "soft keys."

A numeric and Special Function Keypad is located directly below the row of eight unlabeled keys. Each key generates an audible tone when pressed. This Membrane Keypad contains the following numeric and special function keys:

- Numeric keys — a block of ten numeric keys, labeled from 0 to 9, which are used to enter numeric data
- Enter key — stores entered numeric data and advances the cursor to the next entry location
- Asterisk (*) key — allows the operator to escape (abort) data entry before it is completed
- Arrow keys — a set of four keys used to move the cursor in the direction depicted by each arrow
- Pound (#) key — used for service functions only

PC Keyboard

A PC Keyboard is used to enter alphanumeric data.

Audio

An audio device is used to emit a beep when keys are pressed and to alert the operator when certain events occur.

Reagent System

Introduction

The Reagent System is formulated specifically for the CELL-DYN 1700 Series Systems in order to provide optimal system performance. Use of reagents other than those specified in this manual is not recommended, as instrument performance can be affected. Each CELL-DYN 1700 Series System is tested at the factory using the specified reagents, and all performance claims are generated using these reagents.

CELL-DYN Reagents

Diluent

CELL-DYN Diluent is formulated to meet the following requirements:

- Act as the diluent for the WBCs, RBCs, PLTs, and Hemoglobin.
- Maintain the cell volume of each red blood cell and platelet during the count and sizing portion of the measurement cycle.
- Provide a conductive medium for impedance counting of cells and platelets.
- Rinse the Sample Probe.

Lytic Agent

CELL-DYN Lytic Agent is formulated to meet the following requirements:

- Rapidly lyse the red blood cells and minimize the resultant cell stroma.
- Alter the white cell membrane to allow the cytoplasm to slowly diffuse and allow the membrane to shrink around the nucleus and any granules that may be present.
- Convert hemoglobin to a modified hemiglobincyanide complex that is measurable at 540 nm. (The quaternary ammonium lysate participates as a chromagen.)

Detergent

CELL-DYN Detergent is formulated to meet the following requirements:

- Provide an optically clear solution that is used to obtain the Zero Reference during the Hemoglobin Measurement Cycle.
- Provide proper meniscus formation in both metering tubes and maintain it during each run cycle.
- Rinse both counting chambers, both metering tubes, and the HGB Flow Cell with minimal bubble formation.

Enzymatic Cleaner

CELL-DYN Enzymatic Cleaner is formulated to effectively remove protein buildup within the instrument.

Reagent Storage

Reagents must be stored at room temperature to ensure optimal performance, except the Enzymatic Cleaner, which should be stored at a temperature between 2 and 8°C (between 36 and 46°F). All reagents should be protected from direct sunlight, extreme heat, and freezing during storage. Temperatures below 0°C (32°F) may cause reagent layering that changes the tonicity and conductivity of the reagents. If any reagent has been frozen, it should not be used.

Each length of Reagent Inlet Tubing has a cap attached that minimizes evaporation and contamination during use. Ensure that all reagent caps are securely attached to reagent containers during use. However, reagent quality may still deteriorate with time. Therefore, use all reagents within the dating period indicated on the label.

Reagent Handling

When handling reagents, attention should be directed to the following:

1. Always wash your hands after handling reagents.
2. Wear rubber gloves when handling reagents for an extensive time period.
3. Never transfer the contents of a reagent container to an unmarked container.
4. Thoroughly clean all spills. Remove any dried residue in and around the Reagent Inlet Connectors located on the Left Side Panel of the instrument.
5. Dispose of reagents and waste fluids according to federal, state, and local ordinances.

Background Count

Always run a background count after installing a fresh container of reagent.

Consumables

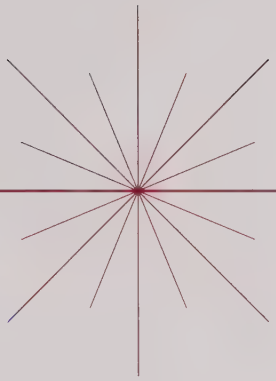
The following consumables are also used with the CELL-DYN 1700 System:

- Micropipettes
- Printout tickets
- Graphics paper
- Printer Ribbons
- DYN-A-WIPE™ lint-free pads
- Enzymatic Cleaner Concentrate

For information on ordering parts and accessories, reagents, controls, calibrators, and consumables, please refer to ***Appendix A — Parts and Accessories.***

ABBOTT

CELL-DYN® 1700 SYSTEM



Installation Procedures and Special Requirements

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Installation Procedures and Special Requirements

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NOTES

Overview

Installation of the CELL-DYN® 1700 System should be performed by an Abbott-authorized representative to ensure that all system components are functioning correctly and to verify system performance. Installation procedures must be repeated if the System is moved from the original installation site.

> NOTE: Installation of the System by an unauthorized or untrained person could result in damage to the system and may void the warranty. Never attempt to install the System without an Abbott-authorized representative present.

This section provides general requirements for a successful installation.

NOTES

Initial Preparation

Inventory

Confirm that the CELL-DYN 1700 System shipment contains the following:

- Instrument (including keyboard)
- Accessory Kit
- Graphics Printer
- Reagents, Calibrator, and Controls necessary for installation

If you ordered a second printer for ticket printing, also confirm that you received it.

Accessory Kit

Confirm that the Accessory Kit contains the following:

- Operations Manual
- Keyboard Cover
- Fuse, SB 2.5 amps 220/240 V (2)
- Fuse, SB 5.0 amps 110/120 V (2)
- Printer Paper 9.5" x 11"
- Power Cord
- Allen Wrench 3/32"
- Allen Wrench 7/64"
- Aperture Brush
- Reagent Line Kit
- Printer Stand
- Printer Cable
- Large Peristaltic Pump Tubing (CS model only)

Visually inspect these items for damage. If there is any damage, contact the Abbott Customer Support Center.

Unpacking

Remove the instrument from the shipping container and visually inspect for damage. If there is any damage, contact the Abbott Customer Support Center.

Space Requirements

Select an appropriate location for the CELL-DYN 1700 System.

Approximately four (4) linear feet of countertop space is required. Allow sufficient space on the countertop or below the instrument for the diluent, lyse, and detergent containers. Provide space below the instrument for the waste container (if one is used).

Allow at least six (6) inches of space behind and on each side of the instrument for air flow. If possible, allow twenty-four (24) inches of space above and to either side of the instrument for service access. A constant circulating internal air stream is required to cool circuitry and components whenever the power is ON. Do not block the fans.

> **NOTE:** To ensure the instrument and reagents function properly, it is important to maintain the temperature between 59 and 95°F (15 and 35°C).

Locate the instrument:

- On a stable, level surface.
- On a nonporous, nonabsorbing work surface and flooring that can be easily cleaned and disinfected using recommended procedures.
- Away from direct sunlight.
- Away from the path of a cooled air or heated air outlet.
- Away from any other instruments that may interfere with it, such as a centrifuge, any X-ray equipment, a CRT, a video terminal, a computer, or a copier.

Place the reagents on the same level as or below the instrument.

Waste Requirements

Allow room for a suitable waste container below the unit, or position the instrument to permit the waste to be routed directly to a drain. The drain must be suitable for disposal of waste with *possible biological and chemical hazard.* Be sure that the waste outlet tubing is secured in the drain hole. (For installation instructions, refer to ***Installation, Tubing and Diluent Syringe Installation*** within this section.)

Regulations on permissible substances, and their amounts, for disposal in public sewer systems vary from state to state and even community to community. Customers are advised to be knowledgeable of all applicable local, state, and federal requirements, and the contents of their effluent streams, before disposal of waste in public sewer systems.

Power Requirements

Be sure that the system is located at the desired site before attempting any connections. A grounded power outlet is required. A voltage regulator may be necessary for optimum performance. The following table shows the power source requirements for the instrument. Insert the Power Cord into the Power Cord Connector on the Rear Panel. *Do not turn the power ON at this time.* Proceed with installation.

⚠ **CAUTION:** Check all side and rear panel connectors for particles or foreign material that can impair electrical contact when connections are made.

Nominal Line Voltage	Operative Range	Operating Cycles
100	90 – 110 VAC	50/60 Hz
120	110 – 130 VAC	50/60 Hz
220	200 – 240 VAC	50/60 Hz
240	220 – 260 VAC	50/60 Hz

The CELL-DYN 1700 is designed for low power consumption. The instrument automatically performs an Initialization cycle whenever power is turned ON. During the daily routine operating period, power should be left ON.

NOTES

Installation

Printer Installation

Overview

Remove the printer from the shipping container and visually inspect for damage. If there is any damage, contact the Abbott Customer Support Center. Find a suitable location adjacent to the instrument. Be sure that the Printer Power Switch is in the OFF position. The printer manuals should be stored in a convenient location.

> **NOTE:** If the printer is placed on top of the instrument, be sure that the paper does not restrict air flow to the Rear Panel Fans.

When plugged into the Graphics Printer Port as shown in the following figure, the dot matrix printer prints graphics reports. When plugged into the Ticket Printer Port, the same printer (or a second dot matrix printer) prints individual preprinted tickets. Abbott recommends using two printers if both graphics and ticket output are required.

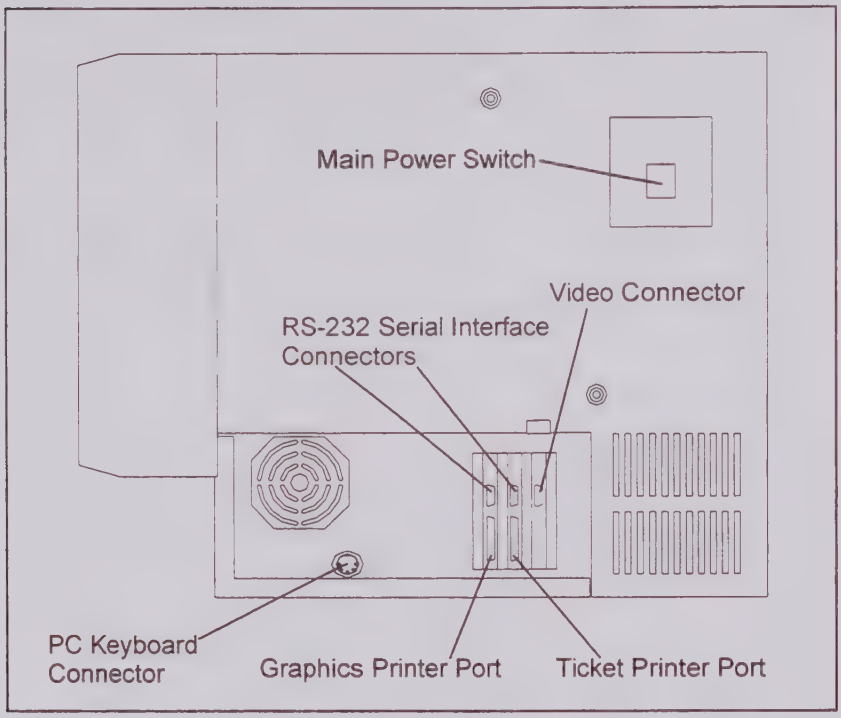

Figure 2.1: Interface (Right Side) Panel

Follow installation instructions carefully to be sure that the printer(s) is connected to the correct port on the instrument. For convenience, general instructions are provided for loading individual preprinted tickets in the dot matrix printer when printed tickets are desired. For a detailed description of the printer components and operating instructions, refer to the manuals that accompany the printer.

Graphics Printing

The Graphics Printer is an OKIDATA® MICROLINE® 320 or compatible printer.

1. Assemble the printer as directed in the printer manual.

2. Make sure that the Printer Power Switch is OFF. Plug the Power Cord into the printer. Do not plug the other end into a grounded outlet until you are ready to power ON.
3. Locate the interface cable in the Accessory Kit and attach it to the Graphics Printer Port on the Interface Panel. (Refer to the previous figure.) Attach the cable's other end to the printer's rear panel connector. Refer to the printer's operations manual for detailed installation procedures.
4. Install the Ribbon Cartridge as directed in the printer manual.
5. Load the paper as directed in the printer manual.
6. Plug the Power Cord into a grounded outlet and turn the Power Switch ON.

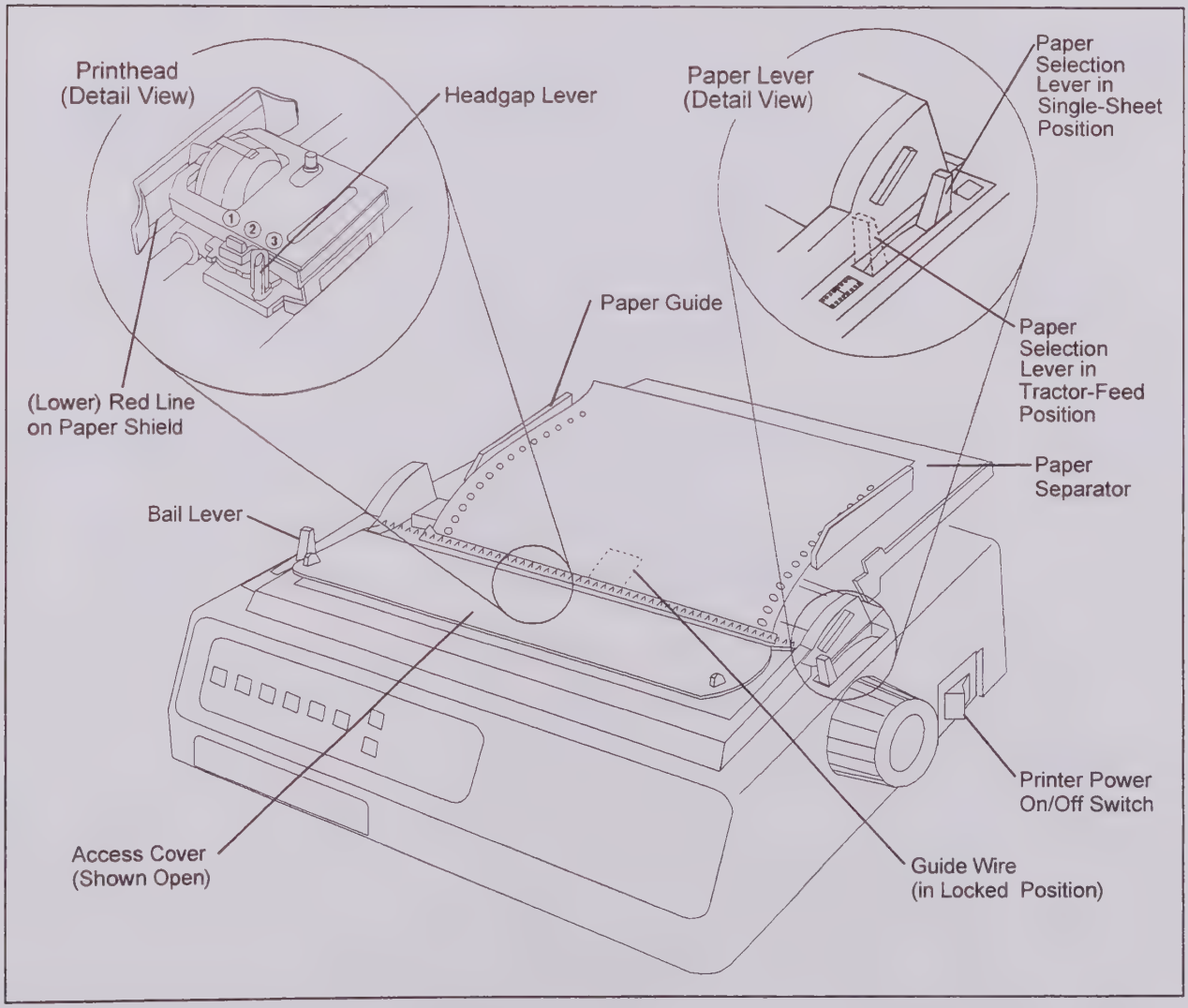

Figure 2.2: OKIDATA® MICROLINE® Printer

Self-Test Printouts

Run self-test printouts before using the printer for the first time. These self-tests may be run any time to verify proper printer operation.

> NOTE: The CELL-DYN 1700 software automatically controls and adjusts most print conditions for the Graphics Printer, including page width. Occasionally, a few settings may need to be changed in the printer's software for correct operation. If printing is not what you expect, refer to the printer manual for guidance in making adjustments or understanding self-test printouts. If you have additional questions or experience any problems, call the Abbott Customer Support Center for assistance.

Ticket Printing

The printer connected to the Ticket Printer Port is used to print result data on 3.25-inch wide, multiple copy, carbon or carbonless tickets. A second OKIDATA® MICROLINE® 320 or compatible printer is recommended for printing tickets.

1. Assemble the printer as directed in the printer manual.
2. Make sure that the Printer Power Switch is OFF. Plug the Power Cord into the printer. Do not plug the other end into a grounded outlet until you are ready to power ON.
3. Locate the interface cable in the accessory kit and attach it to the Ticket Printer Port on the Interface Panel. (Refer to Figure 2.1, Interface [Right Side] Panel.) Attach the cable's other end to the printer's rear panel connector. Refer to the printer's operations manual for detailed installation procedures.
4. Install the Ribbon Cartridge as directed in the printer manual.
5. Load the paper as directed in the printer manual.
6. Plug the Power Cord into a grounded outlet and turn the Power Switch ON.

Self-Test Printouts

Run self-test printouts before using the printer for the first time. These self-tests may be run any time to verify proper printer operation.

> NOTE: The CELL-DYN 1700 software automatically controls and adjusts most print conditions for the Ticket Printer, including page width. Occasionally, a few settings may need to be changed in the printer's software for correct operation. If printing is not what you expect, refer to the printer manual for guidance in making adjustments or understanding self-test printouts. If you have additional questions or experience any problems, call the Abbott Customer Support Center for assistance.

> NOTE: The CELL-DYN 1700 System must be reinitialized prior to the initial ticket printing operation.

Instructions are given below for loading individual tickets.

1. Be sure that the printer cable is connected to the Ticket Printer Port and the power is turned ON.
2. Set the Ribbon Cartridge Headgap Lever to adjust for the thickness of the tickets. (Refer to the previous figure.)
3. Move the Paper Selection Lever to the rear position to select single-feed paper.
4. Open the Access Cover and be sure the Guide Wire on the Paper Separator is pushed back into the locked position.
5. Raise the separator to its upright position.
6. Place a ticket on the Paper Separator and adjust the guides so that they barely touch the edges of the ticket.
7. Pull the Bail Lever (on the left) forward. The ticket will automatically feed into place. Release the Bail Lever.
8. Press **[SEL]** to deselect the printer (**SEL** indicator is not illuminated) and set the Top of Form by pressing and holding the **[TOF/QUIET]** key and pressing the **[FORM FEED]** key to move the ticket up, or pressing the **[LINE FEED]** key to move the ticket down. (The ticket moves in very fine increments so it can be precisely positioned.)

   > NOTE: The ticket will only move down to a certain point to prevent potential ticket jams. Do not move the top of the ticket below the Paper Bail.

9. Position the ticket so that the (lower) red line on the Paper Shield (located between the Print Head and the paper) is positioned where the first line of printing should occur.

   NOTE: When the Top of Form is set, the position is retained in the printer memory until it is reset.

10. Press the [SEL] key to select the printer. The printer is now ready to print.

Tubing and Diluent Syringe Installation

Reagent and Waste Tubing

1. Locate the reagent inlet tubing in the Accessory Kit.
2. Inspect each length of tubing carefully for damage or cracks.
3. Attach the nonweighted end of the tubing with the **Green Detergent** label to the **Green** Connector on the Left Side Panel of the instrument. (Refer to the figure below.) Wipe the outside of the tubing with a damp lint-free pad (such as DYN-A-WIPE™) and place the weighted end into the container of CELL-DYN Diff-Screen Detergent. Secure the cap. *Place the container on the same level as or lower than the unit.*

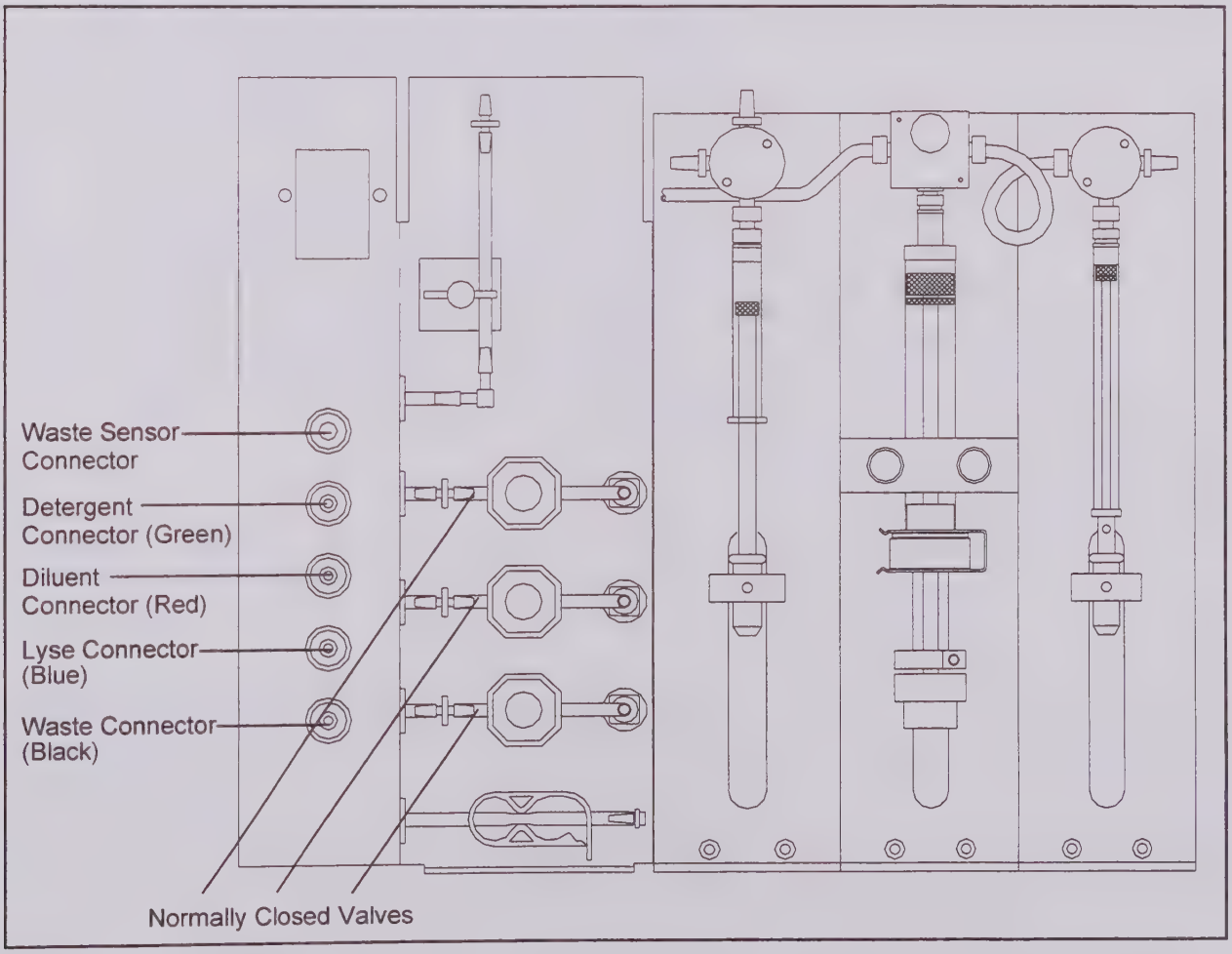

Figure 2.3: Reagent Inlet Panel

4. Attach the nonweighted end of the tubing with the **Red Diluent** label to the **Red** Connector. Wipe the outside of the tubing with a damp lint-free pad (such as DYN-A-WIPE™) and place the weighted end into the container of CELL-DYN Diff-Screen Diluent. Secure the cap. *Place the container on the same level as or lower than the unit.*

5. Attach the nonweighted end of the tubing with the **Blue Lyse** label to the **Blue** Connector. Wipe the outside of the tubing with a damp lint-free pad (such as DYN-A-WIPE™) and place the weighted end into the container of CELL-DYN Lytic Agent Diff-Screen. Secure the cap. *Place the container on the same level as or lower than the unit.*

6. Attach the **Waste Outlet Tubing** to the **Black** Connector. Place the end of the tubing with the cap and sensor into the waste collection container. Ensure that the waste collection container is adequately labeled. Secure the cap, or remove the cap from the tubing and place the tubing into a drain suitable for collection of waste with *possible biological and chemical hazard*. Be sure that the tubing is secured to the drain hole.

7. Locate the **Waste-Full Sensor** Plug attached to the cap's electrode wires. Insert the plug into the **Waste Sensor** connector located on the Reagent Inlet Panel. When the waste tubing is placed directly into a drain, insert a dummy plug into the **Waste Sensor** Connector. If a dummy plug is not inserted, the **Waste Full** alert is activated. For information on ordering a Waste Dummy Plug, refer to ***Appendix A — Parts and Accessories***.

Normally Closed Valves

Before shipment, the tubing for the three Normally Closed Valves on the Left Side Panel is removed. Follow the directions below to reinsert the tubing.

1. Locate the lower Normally Closed Valve (black octagon). Carefully stretch the tubing between your hands and insert it into the slot at the top of the valve. Work the tubing firmly back and forth with a flossing motion until it is completely inserted into the valve and resting on the bottom of the slot. For proper placement of the tubing, refer to Figure 2.5, Diluent Normally Closed Valve.

2. Locate the middle Normally Closed Valve (black octagon). Carefully stretch the tubing between your hands and insert it into the slot at the top of the valve. Work the tubing firmly back and forth with a flossing motion until it is completely inserted into the valve and resting on the bottom of the slot.
3. Locate the upper Normally Closed Valve (black octagon). Carefully stretch the tubing between your hands and insert it into the slot at the top of the valve. Work the tubing firmly back and forth with a flossing motion until it is completely inserted into the valve and resting on the bottom of the slot.

NOTE: Check the tubing on either side of all 3 valves to ensure the tubing is not pinched or crimped and will allow fluid to flow unimpeded. For proper placement of the tubing, refer to Figure 2.5, Diluent Normally Closed Valve.

Diluent Syringe Installation

Before shipment, the Diluent Syringe is removed, cleaned, and reinstalled in the dispenser. It is not attached at the Luer Lock Fitting of the three-way directional valve. A protective cap is attached to the Luer Lock Fitting. Follow the directions below to reattach the Diluent Syringe. Refer to the following figure.

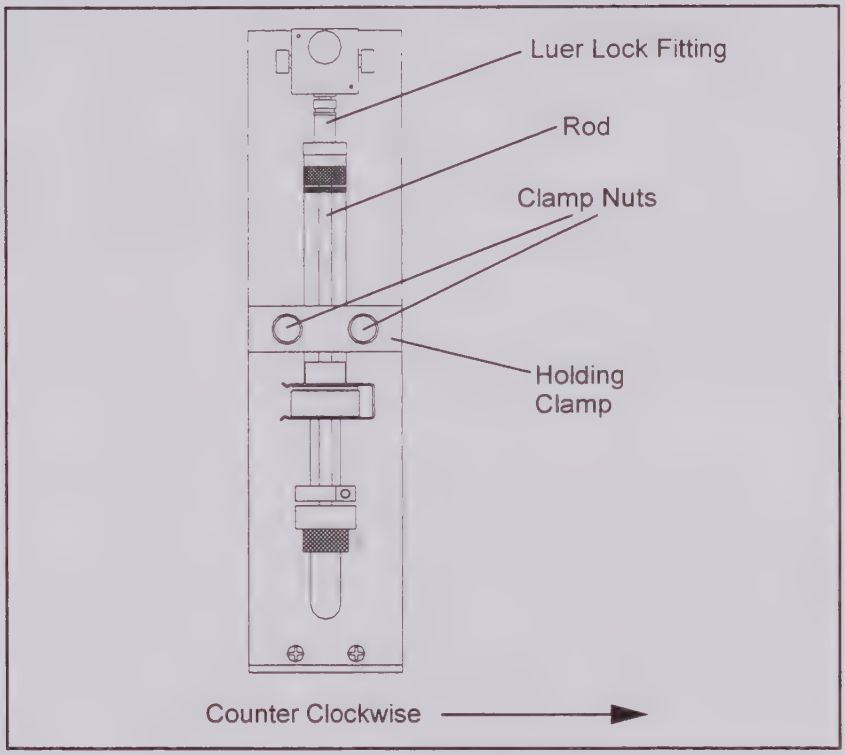

Figure 2.4: Diluent Syringe Assembly

1. Locate the dark-colored plastic cover on the left side of the instrument. Using the two finger holes in the cover, lift the cover up and pull it out to gain access to the Diluent Syringe.
2. Remove the two Clamp Nuts on the Holding Clamp by turning them counterclockwise. Remove the front section of the Holding Clamp. Save the Clamp Nuts and the block.
3. Locate and unscrew the protective cap attached to the Luer Lock Fitting for shipment.
4. Move the barrel of the syringe upward until it touches the Luer Lock thread. Turn the syringe counterclockwise (as viewed from above) until it is securely in place. The syringe should be finger-tight — *do not overtighten.*

5. Replace the front section of the Holding Clamp and secure it with the two Clamp Nuts removed in step 2 above. Tighten the Clamp Nuts finger-tight only.

Flow Panel Inspection and Installation

The Upper Front Cover must be removed to gain access to the Normally Closed Valve on the Flow Panel. Before shipment, the diluent tubing normally inserted in this valve is removed. To ensure correct system operation, this tubing must be completely inserted in the valve before the instrument power is turned ON. Follow the directions below to remove the front covers from the instrument. Refer to the following figure.

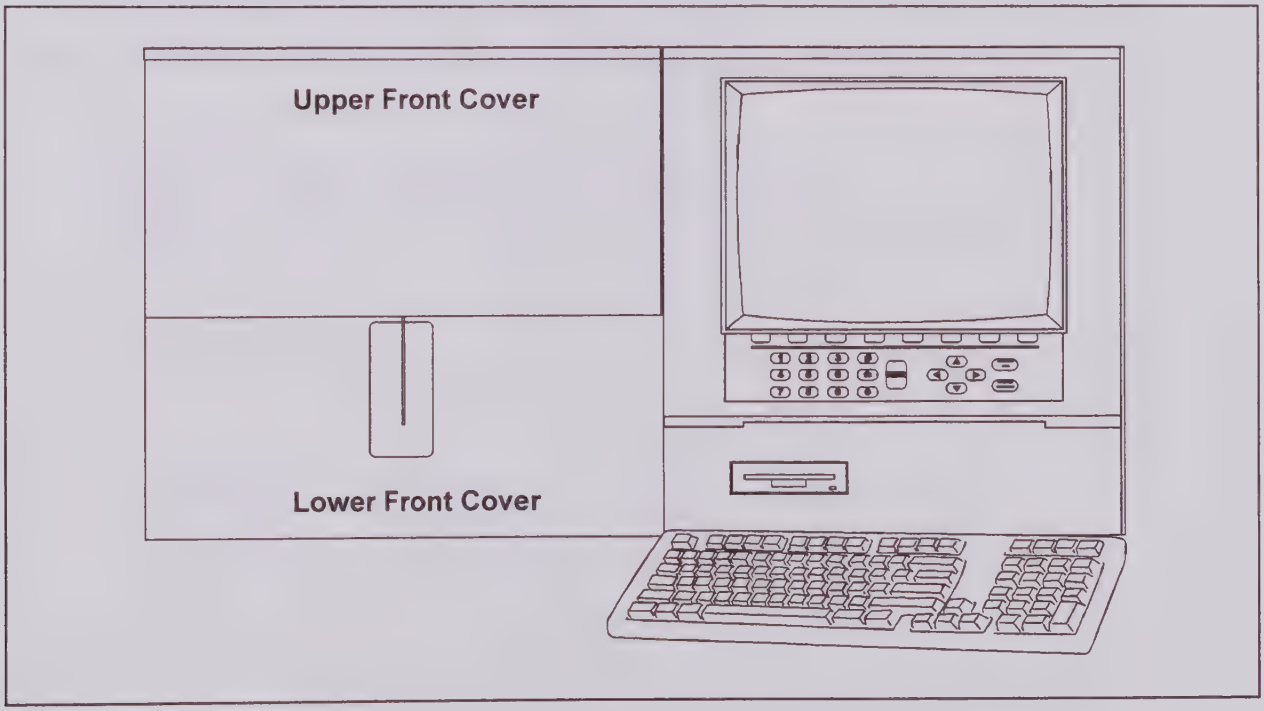

Figure 2.5: **Analyzer Front Covers**

Upper Front Cover Removal

1. Grasp the lower portion of the Upper Front Cover and pull it slightly out (towards you) about 1 inch; then pull the cover up until it releases from the upper mount brackets.
2. To remove the cover completely, detach the Ground Wire at the connector attached to the left side of the Analyzer's main frame. Remove the cover and set it aside.

   NOTE: Performance may be affected if the Ground Wire is not reconnected before the cover is reinstalled.

Lower Front Cover Removal

1. Locate the holding screw on the upper left side of the Lower Front Cover; turn it counterclockwise. Remove the screw and save it. The screw must be reinstalled to ship the instrument. Slide the cover to your left about 1 inch until the right side is free of the screen Bezel Cover.
2. Raise the cover about 1 inch to release the bottom edge from the lower mount brackets.
3. Pull the cover out and set it aside.

Flow Panel Inspection

NOTE: The diluent tubing *must* be installed before the power is turned ON for the instrument to operate correctly. Follow the directions below to install the diluent tubing.

1. Locate, on the upper left portion of the Flow Panel, the Diluent Normally Closed (black octagon) Valve, and the removed diluent tubing. Refer to the following figure.

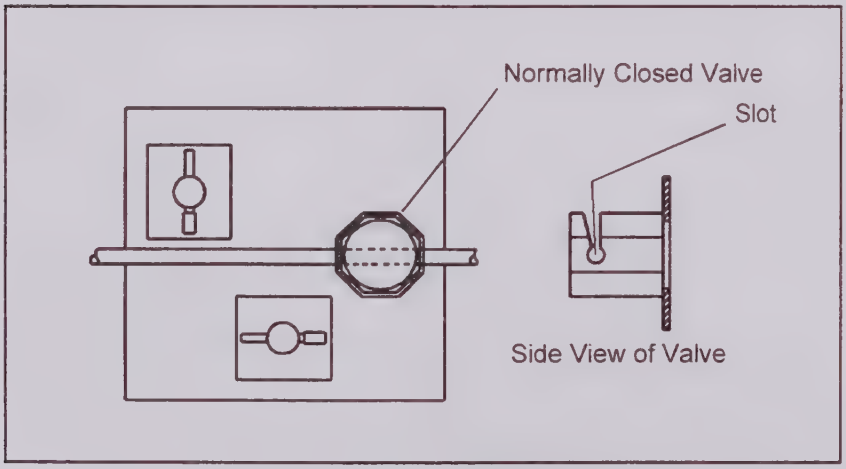

Figure 2.6: Diluent Normally Closed Valve

2. Carefully insert the diluent tubing into the slot at the top of the valve. Work the tubing firmly back and forth with a flossing motion until it is completely inserted into the valve and resting on the bottom of the slot. Unless this tubing is securely seated, the message **Diluent Empty** may be displayed and the flow system will not function properly.
3. Confirm that *both* ends of the diluent tubing are firmly attached to the connectors.

4. Inspect the Flow Panel components for obvious damage and to ensure the following:
   - Tubing is properly positioned under all solenoid pinch valves.
   - WBC and RBC aperture plates are inserted and levers are closed.
5. If there is any damage, contact the Abbott Customer Support Center.
6. When the inspection of the Flow Panel is completed, turn the instrument Main Power Switch ON.

NOTES

Power On

The CELL-DYN 1700 is designed for low power consumption. Whenever the power is applied, an initialization cycle is performed to place mechanical and electrical components in the "home" position, to drain any liquid in the Internal Waste Bottles and Mixing Chambers to the waste system, and when acceptable, to place the unit in the INITIALIZED state.

Power On and Initialization

1. Confirm that the Power Cords for the instrument and the printer(s) are inserted into a line voltage regulator or a grounded power outlet.
2. Turn the printer's Power Switch ON. Confirm that printer paper is installed and feeding correctly.
3. Turn the instrument's Power Switch ON. The screen illuminates within 15 to 30 seconds and the message INITIALIZING appears in the System Status Box located in the upper center of the screen. When the cycle is complete, the message **INITIALIZED** is displayed in the Status Box.
4. To prime the instrument, press the **[PRIME/RUN]** key. This operation primes the flow system with reagents and performs a Normal Background count. Make sure there is no air in the Counting Chambers, no diluent in the Pre-Mixing Cup, and no leakage in the instrument. Then reattach the Upper and Lower Front Covers.

Operator ID Number Entry

An identification number for the current operator is enterable only when the **MAIN MENU** is displayed. When the instrument has been INITIALIZED or is in STANDBY, the **MAIN MENU** is displayed with the cursor flashing at the **<Operator ID>** field.

Type a one- to three-digit ID number using the numeric keys on the Membrane Keypad below the screen or on the PC Keyboard, then press Enter.

> **NOTE:** An operator ID number is not required for system operation.

Sequence Number

The sequence number displayed below the <Operator ID> field automatically increases by one each time a run cycle is initiated by pressing the Touch Plate. The sequence number cannot be entered or changed by the operator.

Setup Instructions

The **SETUP** menu is used to review and change options for data format to output devices such as printers and computers. The units of measure, display, and print format options are also selected from this screen.

ON The function is active.
OFF The function is not active.

Any number displayed in the cursor position can be changed to a new number within the stated limits using the numeric keys on the keypad.

SETUP Menu Screen

The following figure shows the options available on the **SETUP** menu and the soft keys at the bottom of the screen.

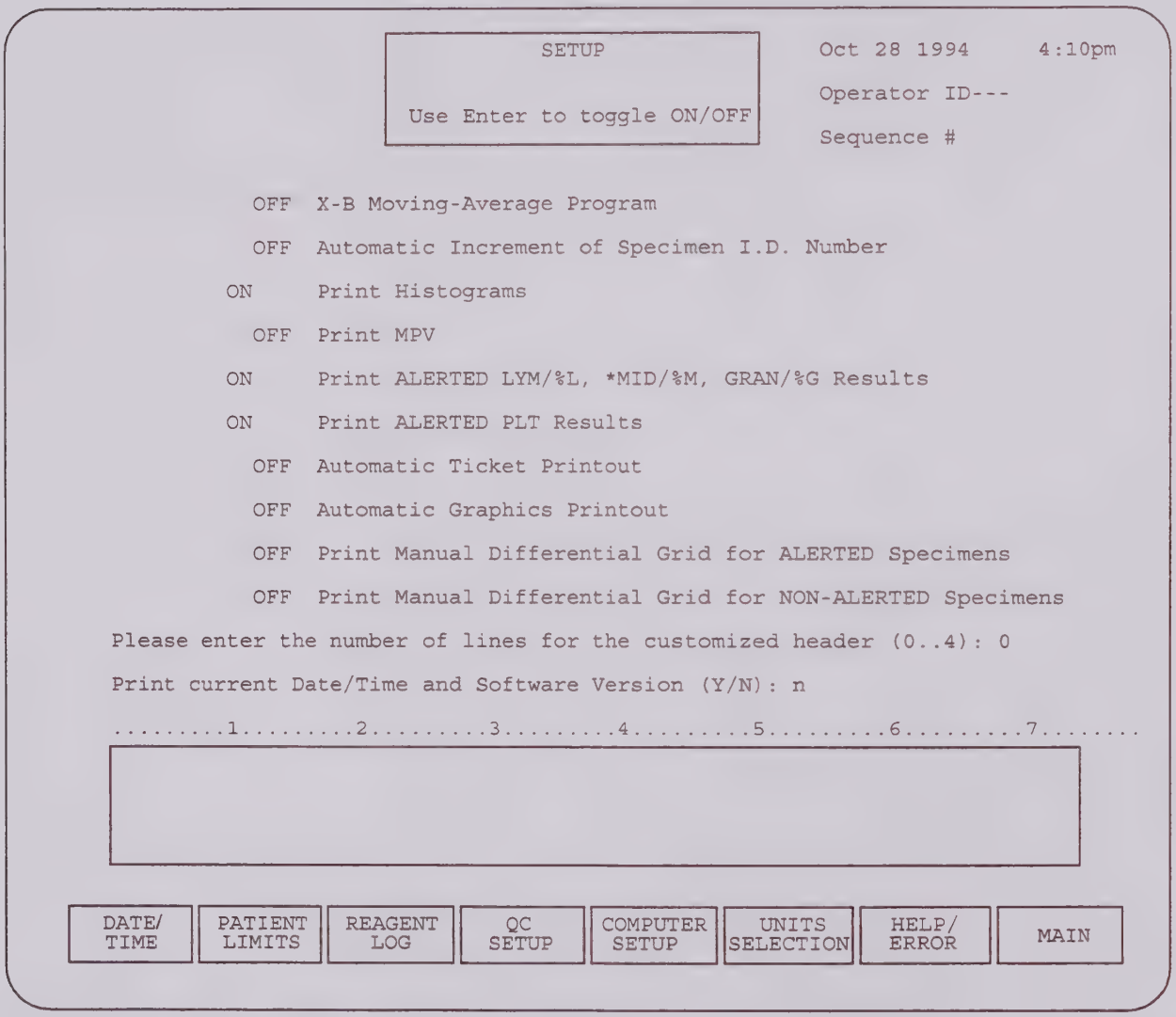
SETUP
Use Enter to toggle ON/OFF
Oct 28 1994 4:10pm
Operator ID---
Sequence #
OFF X-B Moving-Average Program
OFF Automatic Increment of Specimen I.D. Number
ON Print Histograms
OFF Print MPV
ON Print ALERTED LYM/%L, *MID/%M, GRAN/%G Results
ON Print ALERTED PLT Results
OFF Automatic Ticket Printout
OFF Automatic Graphics Printout
OFF Print Manual Differential Grid for ALERTED Specimens
OFF Print Manual Differential Grid for NON-ALERTED Specimens
Please enter the number of lines for the customized header (0..4): 0
Print current Date/Time and Software Version (Y/N): n
.....1.....2.....3.....4.....5.....6.....7.....
DATE/ TIME
PATIENT LIMITS
REAGENT LOG
QC SETUP
COMPUTER SETUP
UNITS SELECTION
HELP/ ERROR
MAIN

Figure 2.7: SETUP Menu

The following options are available on the **SETUP** menu.

1. X-B Moving Average Program — When this option is enabled, the X-B Moving Average Program is activated.
2. Automatic Increment of Specimen ID Number — When this option is enabled, the specimen ID number entered will automatically increase by one for the next sample, unless a new ID number is entered or a different Specimen Type is selected.
3. Print Histograms — When this option is enabled, the WBC, RBC, and PLT histograms are printed with each specimen report.
4. Print MPV — When this option is enabled, the MPV result is printed with each specimen report.
5. Print ALERTED LYM/%L, *MID/%M, GRAN/%G Results — When this option is enabled, the results for these flagged parameters are printed on the specimen report.
6. Print ALERTED PLT Results — When this option is enabled, the results for a flagged PLT are printed on the specimen report.
7. Automatic Ticket Printout — When this option is enabled, a specimen report is automatically printed on the Ticket Printer.
8. Automatic Graphics Printout — When this option is enabled, a specimen report is automatically printed on the Graphics Printer.
9. Print Manual Differential Grid for ALERTED Specimens — When this option is enabled, a specimen report with Manual Differential Grid for ALERTED specimens only will be printed on the Graphics Printer.
10. Print Manual Differential Grid for NON-ALERTED Specimens — When this option is enabled, a specimen report with Manual Differential Grid for NON-ALERTED specimens only will be printed on the Graphics Printer.
11. Number of lines for customized header (0 to 4): — Up to four lines (78 characters) are accepted per entry. This feature applies only to the graphics printout.
12. Print current Date/Time and Software Version — When this option is enabled, the current date, time, and software version are printed. This feature applies only to the graphics printout.

SETUP Menu Options

1. In the **MAIN MENU**, press **[SETUP]**. The **SETUP** menu is displayed. Review and/or change any selection on the **SETUP** menu.

   Press the Enter key to toggle between ON and OFF.

   Enter the number of lines (0 to 4) to be printed from the customized header.

   Enter an N or Y if entering the current day/time and software version.

2. *ARE THE SELECTIONS ACCEPTABLE?*

   YES Go to the Date/Time Setup Procedure.

   NO Use the arrow keys on the keypad to move the cursor to the selection requiring change.

Date/Time Key

Date and time are maintained by an internal battery-powered clock. The current date and time display in the upper right of the screen. The multiple date format option allows the operator to select the desired date format.

- Date reentry is not required when a new format option is selected and the current date is correct.
- When entering a new time, use a 24-hour clock. (For example, 01 for 1 AM, 13 for 1 PM, and 00 for 12 midnight.)

The **DATE/TIME SETUP** menu also allows the operator to activate the Auto Start-Up function and change the time for Auto-Shutdown.

To Change the Date and Time

1. In the **SETUP** menu, press **[DATE/TIME]**.
   The **DATE/TIME SETUP** menu is displayed.
2. *IS THE DISPLAYED DATE FORMAT CORRECT?*

   YES Go to step 3.

   NO Type the number (1–4) for the desired date format option.

3. *IS THE DISPLAYED DATE AND TIME CORRECT?*

   YES Go to step 4.

   The date entry is not required when the date is correct and only the format requires change.

NO Enter the date (using the format selected in step 2 above) and/or the time (using a 24-hour clock).

To Select Auto Start-Up

4. *IS AUTO-START-UP DESIRED?*

YES Press **[AUTO START UP]**. On the **AUTO START-UP** menu, verify that the Automatic Analyzer Start-Up option is ON (with the cursor positioned on this option, use the Enter key to toggle between ON and OFF). Move the cursor to the appropriate space on the Time line. Using a 24-hour clock, enter the hour and minute for automatic start-up of the instrument. Press **[RETURN]**.

Go to step 5.

NO Press **[AUTO START UP]**. Verify that the Automatic Analyzer Start-Up option is OFF. Press **[RETURN]**.

Go to step 5.

To Change Auto Shutdown

5. *IS THE DISPLAYED AUTO SHUTDOWN CORRECT?*

The default time for Auto Shutdown is four hours. The time is displayed in the status box.

YES Press **[RETURN]** twice to return to the **SETUP** menu.

NO Use the arrow keys to place the cursor on the number of idle hours before Auto Shutdown is to occur. Press the Enter key.

Press **[RETURN]** twice to return to the **SETUP** menu.

Patient Limits Key

Upper and lower alert limits for patient specimen results can be entered, reviewed, and changed as required via the [PATIENT LIMITS] key. There are five screens in the PATIENT LIMITS menu: LIMIT SET 1–4 and PANIC LIMITS. Entered values are used to flag patient specimen results for each of the 18 parameters in LIMIT SET 1–4 and for each of the four parameters in PANIC LIMITS (WBC, HGB, HCT, and PLT).

Reference intervals (normal values) for automated blood cell counters are presented in Table B-2 in Appendix B.

For a discussion of the alerts displayed on the screen and printed on the graphics printout when specimen results fall outside the patient limits or panic limits, refer to **Section 3: *Principles of Operation,* Subsection: *Operational Messages and Data Flagging, Parameter Flagging Messages.***

> NOTE: For ticket printout, the information is printed with an asterisk (*).

Entered limits are printed for patient specimen only on the graphics printout.

To Change Patient Limits

1. At the SETUP menu press [PATIENT LIMITS]. The PATIENT LIMITS menu for Limit Set 1 is displayed.
2. *ARE THE LIMITS ACCEPTABLE?*

   YES Go to step 3.

   NO Use the arrow keys to move the cursor to the numbers that are to be changed, and type the new limits. Press the Enter key after each entry to store the data and to automatically advance the cursor to the next field.
3. *DO YOU WISH TO REVIEW LIMIT SET 2, 3, OR 4?*

   YES Press [LIMIT SET 2], [LIMIT SET 3], or [LIMIT SET 4]. For each LIMIT SET menu, use the arrow keys to move the cursor to the numbers that are to be changed, and type the new limits. Press the Enter key after each entry to store the data and to automatically advance the cursor to the next field.

   NO Press [RETURN] to return to the SETUP menu.

4. *DO YOU WISH TO REVIEW PANIC LIMITS?*

   YES Press **[PANIC LIMITS]**. Use the arrow keys to move the cursor to the numbers that are to be changed, and type the new limits. Press the Enter key after each entry to store the data and to automatically advance the cursor to the next field. Press **[RETURN]** twice to return to the **SETUP** menu.

   NO Press **[RETURN]** to return to the **SETUP** menu.

Reagent Log Key

[REAGENT LOG] displays a new screen allowing the operator to select a specific reagent type: diluent, detergent, or lyse. Additional screens allow the operator to enter, review, or print: package size, lot number, expiration date, and open date for up to 12 packages per reagent.

To Complete the Reagent Log

1. At the **SETUP** menu, press **[REAGENT LOG]**. The **REAGENT LOG** menu is displayed.
2. Select a Reagent Log by pressing the appropriate soft key: **[DILUENT LOG]**, **[DETERGENT LOG]**, or **[LYSE LOG]**.

   The selected log screen is displayed with the cursor positioned on the first blank line of the log.
3. Enter the package size, lot number, expiration date, and open date. Press the Enter key after each entry to store the data and to automatically advance the cursor to the next field on the same line. Use only numbers in the fields on this screen.

   Repeat this process until all entries for the Reagent Log are complete.

   NOTE: Type the date entries using the same date format as the system's main **Date/Time** field — seen in the upper right-hand corner of the display. For example, if the main Date/Time format is 29 Jan 1995, then enter 29/01/95 for the date entries.
4. Press **[PRINT LOG]** to print the log.
5. *DO YOU WISH TO SELECT ANOTHER REAGENT TYPE?*

   YES Press **[RETURN]** to return to the **REAGENT LOG** menu.

   Repeat steps 2 through 4 for each reagent type.

   NO Press **[RETURN]** twice followed by **[SETUP]** to return to the **SETUP** menu.

QC Setup Key

The **QC SETUP** menu allows the operator to set up the limits for control files, replicate files, and the X-B Program. There are six functions in QC Setup:

1. X-B Setup — To review or change setup data for the Moving Average Program. MCV, MCH, and MCHC from patient specimens are automatically included when the program is turned ON.
2. Lab ID Setup — To create an identification file for the CELL-DYN user.
3. Low Control — To access four separate files, to turn any of the six Westgard Rules ON or OFF in each of the four files, and to change Range Entry and Mean/Limits in each of the four files.
4. Normal Control — To access four separate files, to turn any of the six Westgard Rules ON or OFF in each of the four files, and to change Range Entry and Mean/Limits in each of the four files.
5. High Control — To access four separate files, to turn any of the six Westgard Rules ON or OFF in each of the four files, and to change Range Entry and Mean/Limits in each of the four files.
6. Replicate File Setup — To access nine separate files, to turn any of the six Westgard Rules ON or OFF in each of the nine files, and to change Range Entry and Mean/Limits in each of the nine files.

X-B Setup Key

X-B Setup is used to review or change the X-B program acceptance ranges, target values, and action limits for the red cell indices (MCV, MCH, and MCHC). Calculated data for each batch (20 specimens) is compared to an established X-B target and limits to determine if the X-B batch data is acceptable. To eliminate bias from grossly abnormal specimen results, data acceptance limits are set, via the **X-B SETUP** menu, to automatically exclude these specimens from the program.

To Use the X-B Function

1. At the **QC SETUP** menu, press **[X-B SETUP]**.

   The **X-B SETUP** menu is displayed, and the cursor is on the MCV lower limit.

2. *ARE THE VALUES ACCEPTABLE?*

   YES Press **[RETURN]** to return to the **QC SETUP** menu.

   NO Move the cursor to the first value to be changed and type the new value. Press the Enter key after each entry to store the data and to automatically advance the cursor to the next field.

   Repeat this process until all values are entered and acceptable.

3. Press **[RETURN]** to return to **QC SETUP** menu.

   NOTE: When the entries are saved, the software checks to see if any entries would result in the upper limit being less than the lower limit. If this situation occurs, the limits are automatically reversed.

Lab ID Setup

The feature enabling the transfer of QC limits and data into a QC file from a floppy disk is not currently available. Therefore the following keys mentioned in this manual should not be used at this time: **[LAB ID SETUP]** and **[WRITE QC TO DISK]**.

Control Setup Key — Low, Normal, High

The Control File Setup function allows the operator to select a specific control file to enter, review, change, or print numeric data pertaining to selected file(s), for example, lot number, expiration date, means and limits, etc. Any run result exceeding these entered limits is highlighted in inverse video on the screen and underlined on the graphics printout. (The parameter result is printed with an asterisk (*) on the Ticket Printer.)

To Select a Specific Control File

1. At the **QC SETUP** menu, press the corresponding key for the type of control to be updated: **[LOW CONTROL]**, **[NORMAL CONTROL]**, or **[HIGH CONTROL]**.
2. Use the arrow keys to select one of four control files displayed.
3. Press **[FILE SETUP]** to display the menu for the file you selected.

4. *IS THE LOT NUMBER ENTRY ACCEPTABLE?*

   YES Press the ↓ arrow key. Go to step 5.

   NO Enter the lot number (digits only, up to nine digits) from the control vial or assay sheet. Press the Enter key to store the data and to automatically advance the cursor to the next field.

5. *IS THE EXPIRATION DATE ENTRY ACCEPTABLE?*

   YES Press the ↓ arrow key. Go to step 6.

   NO Type the expiration date from the control vial or assay sheet and press the Enter key to store the data and to automatically advance the cursor to the next field.

6. *IS THE WESTGARD RULE SELECTION ACCEPTABLE?*

   YES Go to step 7.

   NO Set the cursor at the rule requiring change, and press Enter to toggle between ON and OFF.

   Repeat this process until all rule selections are acceptable.

7. *REVIEW RANGE OR MEAN/LIMITS?*

   YES Press **[RANGE ENTRY]** or **[MEAN/LIMITS]**. The menu for the selected control file is displayed. Go to step 8.

   NO Go to step 11.

8. *DO YOU NEED TO ENTER CONTROL ASSAY VALUES?*

   YES Enter mean values from control assay sheet or enter your own laboratory established mean values. Go to step 9.

   NO Go to step 9.

9. *ARE THE VALUES ACCEPTABLE?*

   YES Go to step 10.

   NO Use the arrow keys to move the cursor to the first value to be changed and type the new value. Press the Enter key to store the data and to automatically advance the cursor to the next field.

   Repeat this process until all values are entered and acceptable.

10. *IS A PRINTOUT REQUIRED?*

    YES Press **[PRINT]**.
    Go to step 11.

    NO Go to step 11.

11. *IS ANOTHER CONTROL FILE SETUP (SAME TYPE) REQUIRED?*

    Example: LOWCTRL2 (after completing LOWCTRL1)

    YES Press **[RETURN]** twice to return to the **XXX CONTROL** menu.

    Repeat steps 2 through 10 for each control as required.

    NO Press **[RETURN]** three times to return to the **QC SETUP** menu. Go to step 12.

12. *IS ANOTHER CONTROL FILE SETUP (NOT THE SAME TYPE) REQUIRED?*

    Example: HIGH CONTROL

    YES Press the corresponding key for the type of control to be updated: **[LOW CONTROL]**, **[NORMAL CONTROL]**, or **[HIGH CONTROL]**.

    The **XXX CONTROL** screen is displayed.
    Repeat steps 2 through 11 for each control as required.

    NO Go to the Replicate File Setup procedure.

Replicate File Setup

The **[Rep File Setup]** key selects a replicate file to set up, displays and prints ranges and means/limits, displays lot number or replicate ID, displays expiration date, and allows the operator to review or change Westgard statistical monitors. Nine replicate files are designated for use with replicate "control" specimens, such as the following:

- Retained patient specimens
- Different shift control specimens
- Different brand of controls
- Precision check specimens

For each file, the operator can enter values for any parameter (up to 18), with mean limits, or upper and lower range.

To Set Up a Replicate File

1. From the **MAIN MENU**, press **[SETUP]**. Press **[QC SETUP]**, then press **[REP FILE SETUP]** to display the **REPLICATES** menu.
2. Select a replicate file using the arrow keys, and press **[FILE SETUP]**. The **REPLICx FILE SETUP** screen is displayed (where x is file 1 through 9).

   NOTE: The **<Lot Number>** field is automatically displayed. To set the **<Replicate ID>** field, press **[REP ID]**.

   If the **<Lot Number>** is displayed, go to step 4, otherwise go to step 3.

3. *IS THE REPLICATE ID NUMBER CORRECT?*

   YES Press the ↓ arrow key.
   Go to step 6.

   NO Enter the replicate ID number (up to 9 digits).
   Go to step 6.

   NOTE: This **<Replicate ID>** field accepts only numeric data. Press the Enter key to store the data and to automatically advance the cursor to the next field.

4. *IS THE LOT NUMBER CORRECT?*

   YES Press the ↓ arrow key.

   NO Type the lot number (digits only) from the control vial or assay sheet. Press the Enter key to store the data and to automatically advance the cursor to the next field.

5. *IS THE EXPIRATION DATE ENTRY ACCEPTABLE?*

   YES Press the ↓ arrow key.

   NO Type the expiration date from the control vial or assay sheet. Press the Enter key to store the data and to automatically advance the cursor to the next field.

6. *IS THE WESTGARD RULE SELECTION ACCEPTABLE?*

   YES Go to step 7.

   NO Set the cursor at the rule requiring change. Press the Enter key to toggle between ON and OFF. The cursor automatically moves to the next rule.

   Repeat this process until all rule selections are acceptable.

   Press the Enter key to store the data and to automatically advance the cursor to the next field.

7. *REVIEW RANGE ENTRY OR MEAN/LIMITS?*

   YES Press **[RANGE ENTRY]** or **[MEAN/LIMITS]** to display the screen for the selected replicate file.
   Go to step 8.

   NO Go to step 10.

8. *ARE THE VALUES ACCEPTABLE?*

   YES Go to step 9.

   NO Use the arrow keys to move the cursor to the first value to be changed and type the new value.

   Press the Enter key to store the data and to automatically advance the cursor.

   Repeat this process until all values are entered and acceptable.

9. *IS A PRINTOUT REQUIRED?*

   YES Press **[PRINT]**.
   Go to step 10.

   NO Go to step 10.

10. *IS ANOTHER REPLICATE FILE REQUIRED?*

    YES Press **[RETURN]** twice to return to the **REPLICATES** menu.

    Repeat steps 2 through 9 for each file, as required.

    NO Press **[RETURN]** until the **SETUP** menu appears.

Computer Setup Key

The Computer Setup function allows the operator to configure the instrument for data transmission to an external computer. In the **SETUP** menu, press **[COMPUTER SETUP]**. Use the Enter key to toggle between ON and OFF. Use the keyboard or soft key to change numeric values. Press **[RETURN]** to return to the **SETUP** menu.

Units Selection Key

The Units Selection function allows the operator to select one of the following four units of measure for specimen results:

1 = FACTORY (United States)
2 = SI
3 = SI (HGB/MCHC in mmol/L, MCH in fmol)
4 = SI (HCT/PCT in %)

NOTE: Verify reference ranges when changing units of measurement.

The default setting is 1 = FACTORY. To select another unit of measure, press **[UNITS SELECTION]** in the **SETUP** menu, type in the appropriate number, and press **[RETURN]** to return to the **SETUP** menu.

This completes Initial Installation, Power On, System Setup, and Initial Prime Procedures.

Calibration, discussed in **Section 6: *Calibration,*** is the next procedure when installing the System. Relocation of the System is discussed in ***Relocation*** within this section.

Relocation

Your CELL-DYN 1700 System has some fragile components, and you must follow this relocation procedure to move the system.

1. Shut down the system according to the procedure described in **Section 9: *Service and Maintenance*, Subsection: *Non-Scheduled Maintenance Procedures, Preparing the Analyzer for an Extended Period of Non-Use or for Shipping***.
2. Prepare the new area before moving the system. Refer to the following subsections within ***Initial Preparation*** at the beginning of this section:
   - Space Requirements
   - Waste Requirements
   - Power Requirements
3. Move the CELL-DYN 1700 system to the new location.

   ⚠ **WARNING:** The instrument weighs 145 pounds. Obtain needed assistance when you lift it.
4. Install the system in the new location according to ***Installation*** within this section.
5. Turn the instrument ON according to ***Power On*** within this section.

   NOTE: All system and hematology data file information is saved, even when the power is OFF, including date, time, and calibration.
6. Verify that the background counts are acceptable before running controls. If background counts or controls are unacceptable, refer to **Section 10: *Troubleshooting*** and follow established laboratory operating procedures.

NOTES

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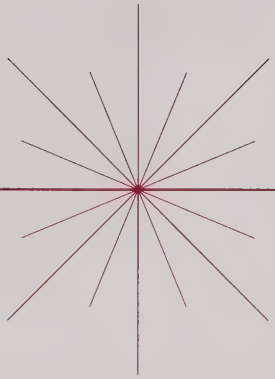
CELL-DYN® 1700 SYSTEM



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Performance Characteristics and Specifications

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Overview

This section is a collection of detailed information about the CELL-DYN® 1700 System.

Included in this section are:

- Physical Specifications
- Power Specifications
- Operational Specifications
- Measurement Specifications
- Performance Specifications
- Performance Characteristics

Interface specifications are not included in this section but can be obtained by calling the Abbott Customer Support Center at 1 (800) CELL DYN.

NOTES

Physical Specifications

The physical dimensions for the CELL-DYN® 1700 are listed in the following two tables.

Table 4.1: Physical Dimensions

Dimension	Instrument	Graphics Printer
Height	19" (49 cm)	5" (13 cm)
Width	34" (87 cm)	16" (41 cm)
Depth	24" (61 cm)	14" (36 cm)
Weight	145 lbs (66 kg)	16 lbs (7 kg)

Table 4.2: Dimensions After Packaging for Shipment

Dimension	Instrument	Graphics Printer
Height	30" (76 cm)	9" (23 cm)
Width	42" (107 cm)	22" (56 cm)
Depth	32" (81 cm)	20" (51 cm)
Weight	200 lbs (91 kg)	35 lbs (16 kg)

NOTES

Data Module

Data Display

A 14-inch diagonal color Video Display Monitor displays all alphanumeric and graphics data, screen labels, and system and specimen alerts.

Membrane Keypad

A row of eight pressure-sensitive keys, each with an audible beep indicator, is located directly below the screen. These are also called "soft keys."

A numeric and special function keypad is located directly below the row of eight unlabeled keys. Each key generates an audible tone when pressed. This Membrane Keypad contains the following numeric and special function keys:

- Numeric keys — a block of ten numeric keys, labeled from 0 to 9, which are used to enter numeric data
- Enter key — stores entered numeric data and advances the cursor to the next entry location
- Asterisk (*) key — allows the operator to escape (abort) data entry before it is completed
- Arrow keys — a set of four keys used to move the cursor in the direction depicted by each arrow
- Pound (#) key — used for service functions only

NOTES

Graphics Printer

An external dot matrix printer provides alphanumeric and graphics reports for displayed and stored data.

NOTES

Power Specifications

Power input requirements for the instrument and printer are shown in the following two tables.

Table 4.3: Power Specifications — Instrument Input Requirements

Range	Frequency
90–260 VAC	50/60 Hz

Table 4.4: Power Specifications — Printer Input Requirements (Ticket Printer or Graphics Printer)

Setting	Frequency
120 VAC	50/60 Hz

Power Consumption

Instrument:

Average: 410 Watts (1460 BTU per hour)
Maximum: 600 Watts (2130 BTU per hour)

NOTES

Operational Specifications

Operating Environment

Temperature:	15 to 30°C (59 to 86°F)
Relative Humidity:	10% to 85%, noncondensing

Cycle Times (READY to READY)

The cycle times in the normal condition are equal to or less than:

• Auto Start-Up:	250	seconds
• Run — Open Mode:	60	seconds *
• Run — Pre-Dilute Mode:	60	seconds
• Auto-Calibration:	60	seconds
• Auto Shutdown:	220-300	seconds

* In the Open Mode with no platelet recount. A run cycle in the Open Mode with a platelet recount is equal to or less than 90 seconds.

Aspiration Volumes (Whole Blood)

• Open Mode	30 µL
• Pre-Dilute Mode:	40 µL

NOTES

Measurement Specifications

Measurement Channels

The instrument has two impedance channels, one for WBC impedance count and one for RBC and PLT.

WBC and Differential

- Method: Electrical Impedance with volumetric metering
- Aperture Size: 100 µm in diameter x 60 µm in length
- Dilution: One part whole blood in 284 parts diluent and lyse

RBC and PLT

- Method: Electrical Impedance with volumetric metering
- Aperture Size: 60 µm in diameter x 70 µm in length
- Dilution: One part whole blood in 12,800 parts diluent

HGB

- Method: Modified cyanmethemoglobin with autoblank
- Light Source: LED
- Wavelength: 540 nm
- Dilution: One part whole blood in 284 parts diluent and lyse

NOTES

Performance Specifications

CELL-DYN 1700 performance has been verified during evaluations performed on systems operated at Abbott Diagnostics and during evaluations performed with systems installed and operated in hematology laboratories at selected clinical sites.

> **NOTE:** Stated performance specifications apply only when the CELL-DYN 1700 System is maintained and operated in accordance with the stated guidelines in this manual, using the specified diluent, lyse, and detergent reagents. Any system component change (for example, recalibration, reagent brand or lot, etc.) during a period of time can affect the observed results.

Background Counts

Background values must be within the following specifications:

• WBC	≤ 0.5	K/µL
• RBC	≤ 0.05	M/µL
• HGB	≤ 0.1	g/dL
• PLT	≤ 10.0	K/µL

Linearity

Linearity specifications are determined by analyzing dilutions of a commercially available control material that contains no interfering substances and displays no suspect parameter flags. Specifications are determined by taking multiple measurements on each dilution to minimize the effect of imprecision. The stated limits (refer to the following table) are determined by linear regression through the origin (0,0), assuring that the collected data throughout the linear reportable range do not exceed the stated allowable limits in the table.

Table 4.5: Linearity Specifications

Parameter	Linear Reportable Range	*Allowable Limit ± or %
WBC	1.0 – 99.9 K/µL	± 0.4 or 3.0%
RBC	1.0 – 7.00 M/µL	± 0.1 or 2.5%
HGB	2.5 – 24.0 g/dL	± 0.3 or 2.0%
MCV	50 – 200 fL	± 3.0 or 3.0%
PLT	10 – 999 K/µL	± 12 or 4.0%
MPV	5.0 – 20.0 fL	± 1.0 or 3.0%

* Whichever is greater. Applies to actual mean value obtained in reference to the expected value.

Carryover

Carryover is determined by running samples with high concentrations of WBCs, RBCs, HGB, and PLTs. Each sample is run in triplicate followed by three background cycles. The percent carryover is calculated using the following formula:

$$\text{Carryover} = \frac{(\text{Background}_1 - \text{Background}_3)}{(\text{Sample}_3 - \text{Background}_3)} \times 100$$

The following table shows carryover percent for WBC, RBC, HGB, and PLT in both the Open and Pre-Dilute Modes.

Table 4.6: Carryover — Open and Pre-Dilute Modes

	WBC (K/μL)	RBC (M/μL)	HGB (g/dL)	PLT (K/μL)
Level	90.0	6.20	22.0	900
% Carryover	< 1.0	< 0.5	< 0.8	< 1.0

Within Sample Precision

Samples used to verify precision values should have results that fall within the laboratory's reference interval (normal range). These samples should not display any suspect parameter flags.

Hemogram Parameters

Precision is a check on routine instrument operation. The following table presents the precision specifications for the hemogram parameters for specimens run in the Open Mode. The stated CV% in the following table represents the instrument precision at a 95% confidence level from N=20 replicate runs.

Table 4.7: Within Sample Precision of the Hemogram Parameters — Open Mode

Parameter	CV%
WBC	≤ 2.5
RBC	≤ 1.7
HGB	≤ 1.2
MCV	≤ 1.5
PLT	≤ 6.0
MPV	≤ 6.0

Results obtained from samples run in the Pre-Dilute Mode may have an increased level of imprecision due to operator technique.

WBC Differential Parameters

Precision specifications for the WBC Differential parameters are given as a 95% confidence limit for a range of values for each of the WBC subpopulations.

Table 4.8: Precision of the WBC Differential Parameters — Open Mode

Cell Type	Range	95% Confidence Limit
Lymphocyte %	18 – 57%	±3.1%
Mid %	4 – 9%	±1.6%
Granulocyte %	36 – 77%	±3.5%

Accuracy

Evaluation of the accuracy of the CELL-DYN 1700 System in the Open Mode is demonstrated in the following table. These data were computed from correlation analysis of data obtained from Method Comparison studies performed on approximately 100 whole blood samples analyzed against a reference method with similar technology. None of the samples used for the correlation studies exhibited any suspect parameter flags.

Table 4.9: Whole Blood Accuracy Results — Open Mode

Parameter	Range	Correlation Coefficient
WBC	0.5 – 96.5	≥ 0.98
LYM#	0.1 – 94.5	≥ 0.92
MID#	0.0 – 11.4	≥ 0.60
GRAN#	0.1 – 40.8	≥ 0.92
RBC	1.48 – 6.47	≥ 0.98
HGB	4.2 – 18.2	≥ 0.98
HCT	12.5 – 55.3	≥ 0.98
MCV	63 – 113	≥ 0.98
RDW	10.8 – 27.6	≥ 0.92
PLT	11 – 939	≥ 0.98
MPV	6.4 – 15.4	≥ 0.92

Bias

Bias in the case of the CELL-DYN 1700 System is measured by the correlation coefficient, since the restricted range of many hematology parameters precludes the use of the fitted linear regression equation to ascertain the bias magnitude, such as is recommended in NCCLS document EP9-T[1]. Also note that this restricted range, along with the known imprecision of the standard comparative methods, places an upper limit to the degree of correlation that can be expected for several of the parameters.

Mode to Mode Bias

The CELL-DYN 1700 System can be calibrated to agree with reference values within the allowable calibration ranges. Both modes of operation, Open and Pre-Dilute, may be calibrated. Thus, it is possible to compensate for differences between modes due to differing aspiration pathways or operational sequences. When each mode is properly calibrated according to directions given in this manual, bias between modes is clinically insignificant.

Performance Characteristics

Typical Precision

Performance characteristics provide a concise summary of system performance when operated under normal laboratory conditions. The pooled precision values (CV%) for the hemogram parameters Within Sample, shown in the following table, are based on the analysis of data from replicate runs of N=20.

Table 4.10: Typical Within Sample Precision Results — Open Mode

Parameter	Typical Precision Within Sample	
	Range	CV%
WBC (K/μL)	4.4 – 9.0	2.1
RBC (M/μL)	3.78 – 5.60	1.2
HGB (g/dL)	12.2 – 15.9	1.0
MCV (fL)	78 – 97	1.0
PLT (K/μL)	179 – 420	3.2
MPV (fL)	7.4 – 11.5	4.6

NOTES

References

1. National Committee for Clinical Laboratory Standards. *Method Comparison and Bias Estimation Using Patient Samples*. Tentative Guideline. NCCLS Document EP9-T. Villanova, PA. 1993.

NOTES

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CELL-DYN® 1700 SYSTEM

Performance Characteristics and Specifications

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Overview

The principles the CELL-DYN® 1700 System uses to measure, count, and calculate the hematological parameters are discussed in ***Sample Analysis Cycle Overview*** within this section. Subsequent subsections discuss the measurement process for WBC, RBC, PLT, and Hemoglobin. The last subsection, ***Operational Messages and Data Flagging,*** discusses the flags generated by the instrument due to measured parameters outside predefined limits, sample abnormality, interference in the measurement process, or detection of an abnormal subpopulation. Quality Control methodology is discussed in **Section 11: *Quality Control.***

The two independent measurement methods used in the CELL-DYN 1700 System are:

- The Electrical Impedance Method for determining WBC, RBC, and PLT data
- The Modified Cyanmethemoglobin Method for determining HGB

During each count cycle, the sample is aspirated, diluted, and mixed before each parameter is measured.

NOTES

Sample Analysis Cycle Overview

Open Mode

Aspiration

The CELL-DYN 1700 System uses the Open Sample Mode to aspirate 30 microliters (µL) of whole blood from a collection tube that has been opened and held under the Sample Aspiration Probe.

Dilution

A 7.5-milliliter (mL) volume of diluent is added in the Pre-Mixing Cup to achieve a ratio of 1:251.

> **NOTE:** The ratio "1:251" represents 1 part in a *total* of 251 parts, not 1 part *plus* 251 parts.

The diluted sample is then divided into two samples.

- 100 µL of the 1:251 sample dilution are aspirated and mixed with an addition of 5 mL of diluent in the RBC/PLT mixing chamber to a ratio of 1:12801. The 1:12801 dilution is used to analyze the red blood cell and platelet parameters.
- The remainder of the 1:251 dilution is mixed with 1.0 mL of lyse reagent in the WBC Mixing Chamber. The lyse reagent ruptures the membrane of each red blood cell causing cytoplasm and hemoglobin to be quickly released. The red blood cell membrane (ghost) that remains is less than 2 femtoliters (fL).
- The lyse reagent also compresses the membrane of each white cell (leukocyte). This causes cytoplasm to slowly diffuse from the cell as the membrane shrinks around the nucleus and any cytoplasmic granules that may be present. This dilution is used to measure the number and modified size of the white cells and the amount of hemoglobin released.
- Volumetric metering is used in both the WBC Counting Chamber and the RBC Counting Chamber to ensure that a precise amount of diluted specimen is measured during each count cycle.

Pre-Dilute Mode

In the Pre-Dilute Mode, whole blood is pre-diluted with diluent to a ratio of 1:251 (using 40 µL of sample to 10 mL of diluent) and then poured into the Pre-Mixing Cup. The sample is then processed in the same manner as Open Mode. For directions on preparing pre-diluted solutions, refer to **Section 5:** ***Operating Instructions,*** **Subsection:** ***Sample Analysis, Running Samples — Pre-Dilute Mode.***

Reporting Results

Parameter results can be expressed in different terms depending on the unit of measurement selected in **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***SETUP Screen Options, Units Selection Key, Setup Instructions.*** The reporting terms for all parameters under each unit type are listed below.

NOTE: Verify reference ranges when changing units of measurement.

Parameter	Factory[1]	SI[2]	SI[3]	SI[4]
WBC	K/µL	G/L	G/L	$10E^9$/L
LYM	%L	%L	%L	%L
MID	%M	%M	%M	%M
GRAN	%G	%G	%G	%G
RBC	M/µL	T/L	T/L	$10E^{12}$/L
HGB	g/dL	g/L	mmol/L	g/L
HCT	%	L/L	L/L	%
MCV	fL	fL	fL	fL
MCH	pg	pg	fmol	pg
MCHC	g/dL	g/L	mmol/L	g/L
RDW	%	%	%	%
PLT	K/µL	G/L	G/L	$10E^9$/L
MPV	fL	fL	fL	fL
PCT*	%	mL/L	mL/L	%
PDW*	10(GSD)	10(GSD)	10(GSD)	10(GSD)

* Displayed but not printed on the graphics or ticket printout.

1 United States

2 Standard International

3 (HGB/MCHC in mmol/L, MCH in fmol)

4 (HCT/PCT in %)

WBC Analysis

Electrical impedance is used to count the white blood cells as they pass through the aperture in the von Behrens WBC Transducer. As each cell is drawn through the aperture, a change in electrical resistance occurs generating an equivalent voltage pulse. The number of pulses sensed during each cycle corresponds to the number of white cells counted. The amplitude of each pulse is directly proportional to the cell volume.

The CELL-DYN 1700 System uses electronic sizing to determine three distinct white cell subpopulations. Cells correlating to lymphocytes are included in the small cell subpopulation. Cells correlating to granulocytes (neutrophils) are included in the large cell population. The remaining cells correlating to monocytes, basophils, eosinophils, blasts, and other precursor white cells are generally included in the mid-size cell population.

RBC/PLT Analysis

The 1:12801 dilution is pulled through the aperture of the transducer bath where electrical impedance is used to count the red blood cells and platelets as they pass through the aperture.

Hemoglobin Analysis

After the WBCs have been counted and sized, the remainder of the lysed dilution is transferred to the HGB Flow Cell Assembly. In the Flow Cell, the CELL-DYN 1700 System measures the ability of the dilution to absorb light at a wavelength of 540 nm (nanometers).

Results Displayed

All data is transferred to the CELL-DYN 1700 computer for processing. Results are displayed on the **RUN** screen and are identified below the Status Box, according to specimen type. A patient sample is identified by its ID number. Size distribution data for lyse-modified WBCs and subpopulations, for RBCs, and for PLTs are displayed as histograms. The corresponding results from each count are displayed to the left of each histogram.

MCV, HCT, RDW Determination

The CELL-DYN 1700 System determines the mean cell volume (MCV) from the red blood cell size distribution data. The result for hematocrit is calculated from the red blood cell count (RBC) and the mean cell volume value using the following formula:

HCT (hematocrit) = (RBC x MCV) / 10

Red blood cell distribution width (RDW) is the coefficient of variation of red blood cell heterogeneity determined from the red blood cell size distribution data.

MPV, PCT, PDW Determination

An algorithm is used to analyze the platelet histogram to obtain the mean platelet volume (MPV). A result for plateletcrit (PCT) is calculated from the platelet (PLT) count and mean platelet volume as follows:

PCT = (PLT x MPV) / 10

Platelet distribution width (PDW) is the geometric standard deviation (GSD) of the platelet size distribution.

MCH and MCHC Determination

Values for the mean cell hemoglobin (MCH) and the mean cell hemoglobin concentration (MCHC) are calculated automatically whenever appropriate parameters are measured, for example, red blood cell count (RBC), hematocrit (HCT), and hemoglobin (HGB). The following formulas apply:

MCH (mean cell hemoglobin) = (HGB/RBC) x 10

MCHC (mean cell hemoglobin concentration) = (HGB/HCT) x 100

Data Storage

Up to 5000 run cycles are automatically stored in a Data Log on the Hard Disk Drive.

Instrument Rinse

After each count cycle, each element of the instrument is rinsed:

- The Open Sample Aspiration Probe is rinsed externally with diluent (and internally when diluent is dispensed during sample dilution).
- The von Behrens WBC Transducer is rinsed with diluent.
- The von Behrens RBC/PLT Transducer is rinsed with diluent.
- The HGB Flow Cell is rinsed with detergent.

NOTES

WBC Measurement Process

Overview

The Electrical Impedance Method is used for the determination of WBC data. Cells are counted and sized as they pass through the aperture of the von Behrens WBC Transducer.

Electrical Impedance Measurements

WBCs are counted and sized by the Electrical Impedance Method. This method is based on the measurement of changes in electrical resistance produced by a particle suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on each side of the aperture to create an electrical pathway.

As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated is indicative of the number of particles that passed through the aperture. The amplitude of each pulse is essentially proportional to the particle volume.

Each pulse is amplified and compared to internal reference voltage channels. These channels are delineated by calibrated size discriminators to accept only pulses of a certain amplitude. Thus, the pulses are sorted into various size channels according to their amplitude.

Volumetric Metering

An accurate cell count cannot be obtained unless the precise volume of diluted whole blood that passes through the aperture during the count cycle is known.[1] The CELL-DYN 1700 System uses the Volumetric Metering process to regulate the count cycle and to make sure that a precise volume of sample is analyzed for the measurement.

The WBC Metering Assembly contains a precision-bore glass tube fitted with two optical detectors. This tube ensures that a precise amount of diluted specimen is measured during each count cycle. The exact amount is determined by the distance between the two optical detectors.

Detergent is used to create a meniscus in the metering tube. The count portion of the cycle is initiated when the meniscus reaches the upper detector. The count cycle stops when the meniscus reaches the lower detector. The amount of time required for the meniscus to travel from the upper detector to the lower detector is called the Count Time and is measured in seconds. This is displayed on the **RUN** screen. The computer monitors the Count Time to detect any variation from the expected values. Variation may be caused by debris in the aperture, vacuum fluctuation, or air bubbles in the metering tube. If significant variation is detected, the **RUN** screen displays the message **CLOG** or **FLOW ERR**, and no WBC or differential data is displayed. A clog indicates the flow was too slow, most likely caused by debris in the aperture. Flow errors indicate the flow was too fast, often caused by bubbles in the metering tube.

WBC Measurement

The 1:251 WBC/HGB dilution is delivered to the WBC Mixing Chamber where it is bubble mixed with 1.0 mL of lyse reagent. A metered volume of the lysed sample is drawn through the aperture into the Counting Chamber by vacuum. The WBCs are counted by impedance. If the pulse generated is above the WBC lower threshold, it is counted as a WBC.

As cells exit from the aperture, they tend to swirl around and may re-enter the sensing zone and be counted a second time. This causes the counts to be falsely elevated. The divider plate located in the von Behrens WBC Transducer Counting Chamber minimizes the effect of these recirculating cells.

Coincidence Loss Correction

Two or more cells can enter the aperture sensing zone simultaneously during a measurement cycle. The resistance change created in this situation generates a single pulse with a high amplitude and increased pulse area. Thus, it appears that one large cell has passed through the aperture. Consequently, the cell count is falsely decreased. This count reduction, referred to as Coincidence Loss, is statistically predictable because it has a direct relationship to the effective volume of the aperture and the amount of dilution. Each total cell count is automatically corrected for Coincidence Loss.

WBC Parameters

WBC Histograms

The WBC data is plotted in a histogram format with the relative number of cells on the Y axis and the WBC size distribution data on the X axis. Results of each count are displayed to the left of the histogram on the **RUN** screen.

Once the WBC count is determined, the absolute number of cells in each subpopulation is calculated by multiplying that WBC count by the percentage of each subtype. The results are expressed as follows:

- WBC # K / µL (thousands per microliter)
- LYM # K / µL and %
- GRAN # K / µL and %
- MID # K / µL and %

NOTES

RBC/PLT Measurement Process

Overview

The Electrical Impedance Method is used for the determination of RBC and PLT data. Cells are counted and sized as they pass through the aperture of the von Behrens RBC/PLT Transducer.

Electrical Impedance Measurements

RBCs and PLTs are counted and sized by the Electrical Impedance Method. This method is based on the measurement of changes in electrical resistance produced by a particle suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on each side of the aperture to create an electrical pathway.

As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated is indicative of the number of particles that passed through the aperture. The amplitude of each pulse is essentially proportional to the particle volume.

Each pulse is amplified and compared to internal reference voltage channels. These channels are delineated by calibrated size discriminators to accept only pulses of a certain amplitude. Thus, the pulses are sorted into various size channels according to their amplitude.

Coincidence Loss Correction

Two or more cells can enter the aperture sensing zone simultaneously during a measurement cycle. The resistance change created in this situation generates a single pulse with a high amplitude and increased pulse area. Thus, it appears that one large cell has passed through the aperture. Consequently, the cell count is falsely decreased. This count reduction, referred to as Coincidence Loss, is statistically predictable because it has a direct relationship to the effective volume of the aperture and the amount of dilution. Each total cell count is automatically corrected for Coincidence Loss.

Volumetric Metering

An accurate cell count cannot be obtained unless the precise volume of diluted whole blood that passes through the aperture during the count cycle is known.[1] The CELL-DYN 1700 System uses the Volumetric Metering process to regulate the count cycle and to make sure that a precise volume of sample is analyzed for the measurement.

The RBC/PLT Metering Assembly contains a precision-bore glass tube fitted with two optical detectors. This tube ensures that a precise amount of diluted specimen is measured during each count cycle. The exact amount is determined by the distance between the two optical detectors.

Detergent is used to create a meniscus in the metering tube. The count portion of the cycle is initiated when the meniscus reaches the upper detector. The count cycle stops when the meniscus reaches the lower detector.

The amount of time required for the meniscus to travel from the upper detector to the lower detector is called the Count Time and is measured in seconds. This is displayed on the **RUN** screen. The computer monitors the Count Time to detect any variation from the expected values. Variation may be caused by debris in the aperture, vacuum fluctuation, or air bubbles in the metering tube. If significant variation is detected, the **RUN** screen displays the message **CLOG** or **FLOW ERR**, and no RBC/PLT data is displayed. A clog indicates the flow was too slow, most likely caused by debris in the aperture. Flow errors indicate the flow was too fast, often caused by bubbles in the metering tube.

RBC/PLT Measurement

The 1:12801 RBC/PLT dilution is delivered to the RBC/PLT Mixing Chamber where it is bubble mixed. A precise volume of the diluted specimen is drawn through the aperture into the Counting Chamber by vacuum. The RBCs and PLTs are counted by impedance. If the pulse generated is above the PLT lower threshold, it is counted as a PLT. If the pulse generated is above the RBC lower threshold, it is counted as an RBC.

As cells exit from the aperture, they tend to swirl around and may reenter the sensing zone and be counted a second time. This could cause the counts to be falsely elevated. A divider plate located in the von Behrens RBC/PLT Transducer Counting Chamber minimizes the effect of recirculating cells.

RBC Parameters

RBC Histograms

The RBC data is plotted in a histogram format with the relative number of cells on the Y axis and the RBC size distribution data on the X axis. Results of each count are displayed to the left of the histogram on the **RUN** screen.

RBC Count

The RBC count is measured directly. The number of RBCs is expressed as follows:

RBC = # M / μL (millions per microliter)

MCV

The mean cell volume (MCV) is the average volume of the individual red blood cells. The MCV is derived from the RBC size distribution data and is reported in femtoliters (fL).

HCT

The hematocrit (HCT) is the ratio of red blood cells to plasma and is expressed as a percentage (%) of the whole blood volume. The HCT is calculated from the red blood cell count and the mean cell volume as follows:

HCT = (RBC x MCV) / 10

MCH

The mean cell hemoglobin (MCH) is the average amount of hemoglobin contained in the red blood cell. Each MCH result is reported in picograms (pg). The MCH is calculated from the RBC and HGB as follows:

MCH = (HGB/RBC) x 10

MCHC

The mean cell hemoglobin concentration (MCHC) is the ratio of the weight of hemoglobin to the volume of the average red blood cell expressed as grams per deciliter (g/dL). It is calculated from the HGB and the HCT as follows:

$$MCHC = (HGB/HCT) \times 100$$

RDW

Red cell distribution width (RDW) is a measure of the heterogeneity of the RBC population. The CELL-DYN 1700 reports RDW as a percent (%) coefficient of variation. The RDW is derived from the RBC histogram.

RBC Flagging

For RBC flagging information, refer to ***Operational Messages and Data Flagging, Parameter Flagging Messages*** later in this section.

PLT Measurement

Overview

Pulses counted in the RBC/PLT dilution between 2 and 24 fL are included in the PLT data. If the raw PLT count is below a predetermined value, the instrument automatically continues to count PLTs for an extended count period. The results from the two count periods are averaged. The PLT data is plotted as a histogram. An algorithm analyzes the histogram to eliminate interference and thus determine the lower and upper thresholds for the count.

If no interference is detected, the lower and upper thresholds are set at 2 and 24 fL, respectively. If interference is detected, the thresholds float to determine the best separation between the interference and the PLT population. The lower threshold switches between the 2-fL and the 3-fL regions, and the upper threshold switches between the 20-fL and the 24-fL regions. Once the thresholds have been determined, the PLT count is derived from the data between them.

Interference in the upper threshold region is generally caused by microcytic RBCs. Therefore, after the PLT upper threshold has been determined, the data between it and the RBC lower threshold are reevaluated.

If the interference in either threshold region exceeds a predetermined limit, the PLT count is flagged accordingly. The flags are discussed in ***Operational Messages and Data Flagging, Parameter Flagging Messages*** later in this section.

NOTES

PLT Parameters

PLT Histogram

The PLT data is plotted in a histogram format with the relative number of cells on the Y axis and the PLT size distribution data on the X axis. Results of each count are displayed to the left of the histogram on the **RUN** screen.

PLT Count

The platelet count (PLT) is derived from the PLT histogram after the PLT data have been analyzed by the platelet algorithm. The PLT count is expressed as follows:

PLT = # K / μL (thousands per microliter)

MPV

The mean platelet volume (MPV) is derived from the PLT histogram after the PLT count has been determined. The MPV is reported in femtoliters (fL).

PCT

The plateletcrit (PCT) is the product of the PLT and MPV and is analogous to the hematocrit. It is expressed in percent (%) and is calculated as follows:

PCT = (PLT x MPV) / 10

Each PCT result is expressed as milliliters per liter (mL/L). This parameter is displayed but not printed on the graphics or ticket printout.

PDW

Platelet distribution width is a measure of the heterogeneity of the PLT population. It is expressed as a geometric standard deviation. Each PDW xx.x 10 (GSD) result is derived from the platelet histogram data and is expressed as 10 (GSD). This parameter is displayed but not printed on the graphics or ticket printout.

PLT Flagging

For PLT flagging information, refer to ***Operational Messages and Data Flagging, Parameter Flagging Messages*** later in this section.

NOTES

Hemoglobin Measurement

Overview

The Modified Cyanmethemoglobin[2] Method is used for the colorimetric determination of hemoglobin. A sample of the lyse-diluted sample from the WBC Mixing Chamber is used for the HGB measurement. A low-energy LED is used as the light source. A filtered photodetector with a wavelength of 540 nm measures the transmitted light.

Hemoglobin Measurement Process

A zero or blank reading is first obtained on the detergent to provide a Reference. Then the lytic agent lyses the diluted red blood cells and converts the hemoglobin that is released to a cyanide-containing pigment. After the WBC count is completed, the sample is transferred to the Hemoglobin Flow Cell where the hemoglobin sample concentration is measured. The sample enters the Flow Cell from the bottom. This allows any bubbles present to exit the Flow Cell so they will not interfere with the reading.

The LED shines through the Flow Cell and a 540-nm narrow bandwidth filter onto a photodetector. The hemoglobin concentration is directly proportional to the absorbency of the sample at 540 nm. After the hemoglobin reading has been made, the HGB Flow Cell is rinsed with detergent.

The HGB Reference and HGB Sample readings are compared to determine the HGB concentration of the sample.

The HGB result is expressed in grams of hemoglobin per deciliter (g/dL) of whole blood.

HGB Flagging

For HGB flagging information, refer to ***Operational Messages and Data Flagging, Parameter Flagging Messages*** later in this section.

NOTES

Operational Messages and Data Flagging

Overview

Operational messages and data flags appear on the **RUN** menu and on printed reports. The CELL-DYN 1700 System monitors condition and data criteria that may affect the displayed results, and these messages and flags are used to alert the operator. Instructions for interpreting all flags, numeric data, and histogram data should be incorporated into the laboratory's procedure and used to determine the need for further action and/or review of results. Messages are divided into the following two categories:

Instrument Messages

- Fault Conditions
- Status Conditions

Parameter Flagging Messages

- Dispersional Data Alerts
- Suspect Parameter Flags
- Suspect Population Flags

Instrument Fault and Status Conditions

The Instrument Fault and Status Conditions are discussed in **Section 10: *Troubleshooting and Diagnostics.*** These messages are displayed when the instrument detects an inappropriate condition during specimen processing. When necessary, data is suppressed. When any one of these messages is displayed, refer to **Section 10: *Troubleshooting and Diagnostics*** for assistance. Follow the instructions given and take the appropriate corrective action. When the problem is corrected, repeat the specimen.

Flag: **No display for measured parameters.**

Cause: No result is displayed when the measurement count time is unacceptable. A message pertaining to the probable cause is displayed to the right of the affected measurement histogram. When the time for fluid to reach either detector is too long, **CLOG** is displayed. When the time to reach either detector is too short, **FLOW ERR** is displayed.

Action: Press [CLEAR ORIFICE]. Rerun the specimen when the system is in the READY state. If CLOG appears again, follow the instructions in **Section 9: *Service and Maintenance*** to clean the aperture plates. If FLOW ERR appears again:

1. Go to the SPECIAL PROTOCOLS menu.
2. Press [REAGENT PRIME] to refill the Flow System.

Or, consult **Section 10: *Troubleshooting and Diagnostics.***

Parameter Flagging Messages

Dispersional Data Alerts

There are three levels of limits for the CELL-DYN 1700 System. Two are operator-definable: Patient Limits and Panic Limits. The third, Reportable Range, is set by the system software and reflects the extent of the instrument's ability to measure accurately. Patient Limits are established closest to the normal or typical patient results and are set according to the type of patient samples to be run. Panic Limits are set outside the Patient Limits but inside the reportable range. Panic Limits serve to alert the operator that results deviate from the normal range by a significant degree.

If results for a parameter fall between the upper Patient Limit and the upper Panic Limit, the results are highlighted in inverse video (white on blue) on the screen. On the printout, the results are underlined and the letter "H" is printed in the Flag field. If results for a parameter fall between the lower Patient Limit and the lower Panic Limit, the results are highlighted in inverse video (white on blue) on the screen. On the printout, the results are underlined and the letter "L" is printed in the Flag field.

If results for a parameter fall between the upper Panic Limit and the upper Reportable Range Limit, the results are highlighted in inverse video (white on red) on the screen, and the letters "HH" are printed in the Flag field on the printout. If results for a parameter fall between the lower Panic Limit and the lower Reportable Range Limit, the results are highlighted in inverse video (white on red) on the screen, and the letters "LL" are printed in the Flag field on the printout.

If results for a parameter exceed the upper end of the Reportable Range, chevrons (>>>>) are displayed on the screen and print out instead of the numeric result.

Alert messages pertaining to specimens, either patient or QC, are displayed in place of or next to the affected result(s). All **RUN**, **DATA LOG**, and **QC** results for the affected parameter(s) are displayed in inverse video and underlined on the graphics printout. The parameter result is printed with an asterisk (*) on the ticket printout. The name of each flag, the location of the flag on the display, the cause of the flag, and the action to be taken are given in the following explanation.

Flag: **> > > >.** Chevrons are displayed instead of a numeric value for measured parameters.

Cause: The parameter result exceeds the upper end of the Reportable Range.

Action: Dilute externally and run specimen again. (For specific instructions, refer to the ***Troubleshooting Guide*** in **Section 10: *Troubleshooting and Diagnostics.***)

Suspect Parameter Flags

These flags are generated after the instrument evaluates the measured data for a particular parameter or group of parameters. The result may be suspect due to interfering substances or the inability of the instrument to measure a particular parameter due to a sample abnormality. The name of each flag, the location of the flag on the display, the cause of the flag, and the action to be taken are given in the following explanations.

Flag: **LYM RO or RM.** (RM means two or more alert messages.) The alert is displayed between the absolute and percent results of LYM.

Cause: This flag may be caused by:

- Nucleated RBCs
- Platelet clumps
- Giant platelets
- Cryoglobulins
- Incomplete lysis of red blood cells
- CLL (Chronic Lymphocytic Leukemia)
- Fibrin clots

Action: Check specimen for clots. Review a stained smear. *Verify the WBC count by an alternate method.*

Flag: **LRI** — Lower Region Interference.

Cause: This alert is displayed after the PLT result. LRI is generally nonbiological interference. The flag may be caused by:

Debris (dirty aperture)
Contaminated reagent
Electronic noise
Microbubbles

Action: Check the background count. If it exceeds the limits, troubleshoot accordingly. If it is within limits, repeat the specimen. If the flag persists, review a stained smear to determine the cause of the interference and *verify the PLT count.*

Flag: **URI** — Upper Region Interference.

Cause: This alert is displayed after the PLT result. URI is generally biological interference. The flag may be caused by:

Microcytic RBCs
Schistocytes
Giant platelets
Sickle cells
Platelet clumps

NOTE: A "bumpy" platelet histogram may indicate the presence of platelet clumps.

Action: Review the MCV and the PLT histogram. If the MCV is low and/or the histogram indicates an overlap (poor separation in the upper discriminator) in the RBC and PLT populations, review a stained smear to determine the cause and *verify the PLT count.*

Flag: **LRI URI** — Lower and Upper Region Interference

Cause: Interference is present in both the upper and lower regions of the platelet histogram.

Action: Follow the action items given above for the LRI and URI flags.

Suspect Population Flags

These flags are generated when the instrument's evaluation of the measured WBC data indicates the possible presence of an abnormal subpopulation. A stained smear should be reviewed whenever a suspect population flag is present. Therefore, instructions for interpreting flags should be incorporated into the laboratory's review criteria for abnormal samples.

Increased or decreased lytic action can also generate flags.

Flag: **LYM RM.**
Refer to ***Suspect Parameter Flags*** within this section.

Flag: **LYM R1.**
This alert is displayed between the absolute and percent results of LYM.

Cause: This flag may be caused by:

- Lymphocytosis
- Lymphopenia
- Cryoglobulins

Action: Review a stained smear to confirm the results.

Flag: **LYM R2.**
This alert is displayed between the absolute and percent results of LYM.

Cause: This flag may be caused by:

- Lymphocytosis
- Lymphopenia
- Blasts/plasma cells
- Variant lymphocytes
- Basophilia

Action: Review a stained smear to confirm the results.

Flag: **MID R2 or RM.**
(RM means two or more alert messages.) This alert is displayed between the absolute and percent results of MID.

Cause: This flag may be caused by:

- Lymphocytosis
- Lymphopenia
- Blasts/plasma cells
- Variant lymphocytes
- Basophilia
- Monocytosis

Action: Review a stained smear to confirm the results.

Flag: **MID R3 or RM.**
(RM means two or more alert messages.) This alert is displayed between the absolute and percent results of MID.

Cause: This flag may be caused by:

- Eosinophilia
- Blast/plasma cells
- Agranular neutrophils
- Basophilia
- Bands

Action: Review a stained smear to confirm results.

Flag: **GRAN R3 or RM.**
(RM means two or more alert messages.) This alert is displayed between the absolute and percent results of GRAN.

Cause: This flag may be caused by:

- Granulocytosis
- Neutropenia
- Eosinophilia bands
- Agranular neutrophils

Action: Review a stained smear to confirm the results.

Flag: **GRAN R4 or RM.**
(RM means two or more alert messages.) This alert is triggered and displayed between the absolute and percent results of GRAN.

Cause: This flag may be caused by:

Hypersegmented neutrophils
Granulocytosis
Neutropenia
Immature granulocytes

Action: Review a stained smear to confirm the results.

Flag: **No MPV result displayed (data suppressed).**

Cause: The PLT histogram did not meet expected criteria (for example, non-lognormal distribution).

Action: Review a stained smear for abnormal PLT morphology or the presence of PLT aggregates and follow your laboratory's review criteria. *Verify the PLT count.*

NOTES

References

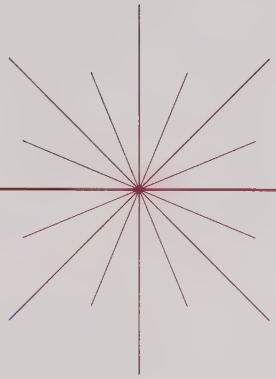
1. International Committee for Standardization in Hematology (ICSH). The Assignment of Values to Fresh Blood Used for Calibrating Automated Cell Counters. *Clinical and Laboratory Hematology* 1988; 10:203-212.

2. The Cyanmethemoglobin Method is approved and recognized by NCCLS (National Committee for Clinical Laboratory Standards).

NOTES

ABBOTT

CELL-DYN® 1700 SYSTEM



Operating Instructions

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Operating Instructions

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Overview

This section, which discusses the operation of the CELL-DYN® 1700 System, is divided into nine major subsections:

- Instrument Start-Up
- Data Module Program Overview
- System Setup Operation
- Specimen Collection and Handling
- Routine Operation
- Sample Analysis
- Using the Data Log
- Daily Shutdown
- Power Off Procedure

The section includes a brief review of the **SETUP** menu. For a more detailed discussion of the setup procedures, refer to **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***Setup Instructions***. Other information dealing with system operations is discussed in the following sections:

Calibration	**Section 6:** ***Calibration Procedures***
Special Protocols	**Section 9:** ***Service and Maintenance***
Troubleshooting	**Section 10:** ***Troubleshooting and Diagnostics***
Quality Control	**Section 11:** ***Quality Control***

NOTES

Instrument Start-Up

The CELL-DYN 1700 Power Switch should be left ON at all times. The instrument has been designed to automatically maintain itself when it is idle. If the instrument is idle for four hours (or other operator-definable duration), an Automatic Shutdown cycle is initiated. The instrument is placed in STANDBY at the end of the Automatic Shutdown cycle.

Power to the printer may be left ON or OFF at the operator's discretion. For complete instructions on printer operation, refer to **Section 12: *Printers.***

A complete procedure for powering the system ON is given in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Power On.*** The procedure to turn the system OFF is given in ***Power Off*** at the end of this section.

Daily Start-Up Procedures

The instrument may be started using the Auto Start-Up function or started manually.

Auto Start-Up Procedure

When the instrument is in the STANDBY state, the Automatic Start-Up cycle will Initialize the instrument, Prime the Flow System, and check the background counts at a specified time each day, bringing the system to the READY state. To activate the Auto Start-Up option, refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions.***

Prior to running patient samples, perform the Daily Quality Control checks as directed in ***System Setup Operation, Daily Quality Control Checks*** within this section.

Manual Start-Up Procedure

To perform Manual Start-Up, do the following:

1. If STANDBY or INITIALIZED is displayed in the **MAIN MENU** Status Box, press **[PRIME/RUN]** to bring the instrument to the READY state.

   NOTE: If the instrument is OFF, first Power ON the system. When **INITIALIZED** is displayed in the Status Box, press **[PRIME/RUN]** to bring the instrument to the READY state.

2. Perform the daily Quality Control checks as directed in ***System Setup Operation, Daily Quality Control Checks*** within this section.

Data Module Program Overview

The Data Module menus are presented as key labels displayed across the bottom of the screen. Each menu is accessed by pressing the soft key on the Membrane Keypad located directly below the label. Alternatively, the operator can access menus by pressing one of the function keys (F1, F2, etc.) on the PC Keyboard. These function keys correspond with the menu labels beginning at the left of the screen and moving to the right. The maximum number of labels is eight; therefore, only the function keys F1 through F8 are used.

When the instrument is powered ON, the **MAIN MENU** is displayed. The key labels displayed across the bottom of this screen are used to access all of the submenus that are available. The **MAIN MENU** soft keys are listed below:

[SETUP]
[PRIME/RUN]
[DATA LOG]
[QUALITY CONTROL]
[CALIBRATION]
[DIAGNOSTICS]
[HELP/ERROR]
[SPECIAL PROTOCOLS]

Main Menu Screen

The **MAIN MENU** screen is divided into four sections:

- The upper left corner shows the current version of the instrument software.
- The Status Box is displayed in the top center of the screen in inverse video. This box appears on every screen to show the following:
  - Menu in use
  - Analyzer status
  - Other applicable information, such as report or file identity, and any existing operator-correctable fault conditions
- The upper right corner shows the current date, time, operator ID, and the sequence number.
- Soft key labels are displayed at the bottom of the screen.

The cursor is positioned at the <OPERATOR ID> field when the **MAIN MENU** is displayed. An operator ID of up to three digits may be entered. This operator ID will be displayed on all other screens and printed on all reports.

System Setup Operation

The **SETUP** menu is used to review and make changes to the following:

- Date and time
- Data formatting on the display screen and to output devices such as printers and computers
- Patient Limits (all eighteen parameters) and the four basic parameters for Panic Limits (WBC, HGB, HCT, and PLT)
- Reagent Logs
- Control files, replicate files, and X-B Program
- Units of measure

ON and OFF are used to indicate if a function is active or inactive. Any number displayed in the cursor position can be changed using the numeric keys on the Membrane Keypad or PC Keyboard to enter a new number within the stated limits. Type an N or Y if entering current Date/Time and Software Version.

The **SETUP** menu is also used to enter or review numeric data, such as date, time, patient specimen limits for alert, control lot number, and target and limits values for control, replicate, and X-B Program files, etc. For a discussion of the **SETUP** menu, refer to **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***Setup Instructions.***

Daily Quality Control Checks

Quality Control checks should be performed on a daily basis according to the laboratory's protocol. Commercial control materials should be properly warmed and mixed according to the manufacturer's recommendations. Patient controls should be handled according to the laboratory's protocol.

> NOTE: If the system has been idle for fifteen minutes or more, a Normal Background should be run immediately prior to running a patient or control sample.

1. In the **RUN** menu, press **[SPECIMEN TYPE]**.
2. Press the soft key for the type of specimen to be run: **[PATIENT SPECIMEN]**, **[QC TYPE]**, **[NORMAL BACKGRND]**, or **[ELECTRICL BACKGRND]**. The type currently selected is displayed in the upper left corner of the screen.
3. Run the control material as directed in the ***Running Samples*** Procedures presented in ***Sample Analysis*** later in this section.
4. Verify that the results are acceptable.

> NOTE: Out-of-range results are displayed in inverse video on the screen and underlined on the printout with an out-of-range indicator. (Refer to **Section 3: *Principles of Operation*, Subsection: *Operational Messages and Data Flagging, Parameter Flagging Messages.***)

5. If the results are unacceptable, repeat the run. If the results are still unacceptable, follow your laboratory's Quality Control procedure for handling out-of-range results and/or refer to **Section 11: *Quality Control.***
6. When the control results are acceptable, patient samples can be analyzed.

Specimen Collection and Handling

Specimen Stability

Fresh whole blood specimens are recommended. The ICSH (International Committee for Standardization in Hematology) defines a fresh blood specimen as one processed within four hours after collection.

Well-mixed whole blood specimens, collected in EDTA anticoagulant and run within eight hours after collection, provide the most accurate results for all parameters. The white cells size distribution may shift when specimens are assayed between five and twenty minutes after collection or more than eight hours after collection.

The stability of capillary specimens collected in micro-collection devices may vary depending on the micro-collection device manufacturer. Refer to the manufacturer's package insert for stability claims.

Specimen Collection

All samples should be collected using proper techniques.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

NOTE: For additional information on collecting venous and capillary samples, refer to NCCLS document H3-A3[1] and NCCLS document H4-A3[2].

NOTES

Routine Operation

The [PRIME/RUN] key on the MAIN MENU is used to display the RUN menu.

> NOTE: When the system is first turned ON or when the system is in STANDBY, the [PRIME/RUN] key is displayed because the instrument is not primed. Once the system has been primed, the [RUN] key is displayed.

The upper left corner of the RUN menu displays the following demographic data fields:

1. <NEXT ID#:> accepts the ID number for the next sample to be run. Up to nine digits (0-9) may be entered. For more information about this feature, refer to ***Sample Analysis*** later in this section.
2. <PATIENT:> accepts the patient's name. Up to sixteen characters may be entered.
3. <SEX (M/F):> accepts sex information of the patient. Only M or F is accepted; all other characters are ignored.
4. <DOB:> accepts the patient's date of birth using the format designated in the SETUP menu.
5. <Dr> accepts the doctor's name. Up to twenty-two characters may be entered.
6. <COLLECTED> accepts the date and time the specimen was taken from the patient. For date, use month and day only. For time, use the format designated in the DATE/TIME setup menu.
7. <COMMENT:> accepts comments. Up to sixteen characters may be entered.

The Status Box is displayed in the top center of the **RUN** menu. It contains the following information:

- Menu in use
- Status of the instrument (for example, READY)
- Fault messages
- Informative messages (during the run cycle) such as the following:
  - **Aspirating**
  - **Dispensing**
  - **Remove specimen**
  - **Counting**
  - **Recount**
  - **Rinsing**

Below the Status Box: Results displayed on the **RUN** screen are identified according to specimen type. A patient sample is identified by the ID number.

Directly below the Status Box: When **[PRE-DILUTE]** is selected, the message **PRE-DILUTE MODE** is displayed in inverse video.

The upper right corner of the **RUN** menu displays the following information:

- Current date and time
- Operator ID — identification of the current operator
- Sequence number — automatically incremented as samples are run
- Limit set (1 to 4, defaults to 1) only when Patient is the selected specimen type
- X-B status if the X-B Program was activated in the **SETUP** menu

RUN Menu

The soft keys displayed across the bottom of the **RUN** menu are used to access the menu options that are available. The **RUN** soft keys are listed below:

[CLEAR ORIFICE] / [CLEAR ALARM]
[PRE-DILUTE]
[SPECIMEN TYPE]
[PARAMETER SELECT]
[PRINT TICKET]
[PRINT REPORT]
[HELP/ERROR]
[MAIN]

Clear Orifice

The **[CLEAR ORIFICE]** key is the default key that appears on the **RUN** menu. When a fault occurs on the instrument, this key changes to **[CLEAR ALARM]**.

[CLEAR ORIFICE] is used to initiate the aperture cleaning sequence that flushes the WBC and RBC/PLT apertures to remove obstructions. When **[CLEAR ORIFICE]** is pressed, the message **CLEARING ORIFICE** is displayed in the Status Box.

Clear Alarm

[CLEAR ALARM] is used to reset the instrument after the operator has corrected the problem. When **[CLEAR ALARM]** is pressed, the message **CLEARING ALARM** is displayed in the Status Box.

Pre-Dilute

[PRE-DILUTE] turns the Pre-Dilute Mode run cycle ON and OFF. The Pre-Dilute Method is used when the amount of blood sample available is insufficient for accurate analysis using the normal run cycle. When ON, the **PRE-DILUTE MODE** message appears directly below the Status Box. This soft key is highlighted in dark blue. The Open Sample Aspiration Probe is raised and placed over the RBC/PLT Mixing Chamber. This allows the operator to remove the Upper Front Cover and pour a pre-diluted 40-µL sample to 10-mL diluent solution into the Pre-Mixing Cup (initial dilution bath). The operator presses the Touch Plate, and the instrument processes the sample.

NOTE: For instructions on removing the Upper Front Cover, refer to **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***Installation, Flow Panel Inspection and Installation***. The procedure for preparing pre-diluted samples and the procedure to calibrate in the Pre-Dilute Mode are discussed in detail in **Section 6:** ***Calibration Procedures,*** **Subsection:** ***Pre-Dilute Method.***

Specimen Type

[SPECIMEN TYPE] is used to select the type of specimen that will be run. When [SPECIMEN TYPE] is pressed, the following soft keys are available:

[PATIENT SPECIMEN]
[QC TYPE]
[NORMAL BACKGRND]
[ELECTRICL BACKGRND]
[HELP/ERROR]
[RETURN]

Patient Specimen

[PATIENT SPECIMEN] is used to run patient samples. Patient identification may be entered on the **RUN** menu after this key is pressed. Results from this run option are stored in the Data Log. Only patient specimens can be included in the X-B Program.

QC (Quality Control) Type

[QC TYPE] is used to select the QC Control Files submenu displaying [LOW CONTROL], [NORMAL CONTROL], [HIGH CONTROL], and [REPLICATES]. Data from these control runs is automatically stored in the designated QC file and in the Data Log.

Normal Background

[NORMAL BACKGRND] is used to select a special Run Mode and to display the background results. Normal Background is used to determine the absence of contaminants and particulates, and the interference of reagents (diluent, detergent, lyse). Results from this run option are identified by the designation **BACKGRD** in the Data Log. A Normal Background should be run immediately prior to running a patient or control sample if the system has been idle for fifteen minutes or more.

Electrical Background

[ELECTRICL BACKGRND] is used to select the Run Mode for Electrical Background counts. Electrical Backgrounds are used to check for electrical interference in the system. (Aperture current is turned OFF during this cycle.) Results from this run option are identified by the designation ELEC BKGD in the Data Log.

Help/Error

See explanation below.

Return

Press [RETURN] to return to the RUN menu.

Parameter Select

[PARAMETER SELECT] allows the operator to choose the parameters to be displayed and printed. The operator can designate all parameters to be ON or OFF or designate individual parameters to be ON or OFF.

Print Ticket

[PRINT TICKET] is used to print the current screen data on a ticket. It is used when the Automatic Ticket Print feature is set to OFF. (When no ticket is in the printer, the message **Ticket Printer NOT Ready/DEV— PRESS HELP/ERROR KEY** appears in the Status Box.)

Print Report

[PRINT REPORT] is selected to print the current screen data on the Graphics Printer. It is used when the automatic graphics print feature is set to OFF. (When no paper is in the printer, the message **Printer NOT READY/ DEV— PRESS HELP/ERROR KEY** appears in the Status Box.)

Help/Error

[HELP/ERROR] accesses a menu that has a [FAULT LOG] key and [HELP] key. If a fault is pending, when [HELP/ERROR] is pressed a list of up to sixteen previous errors will be displayed. Otherwise, pressing [FAULT LOG] allows the operator to view the errors.

Pressing [HELP] allows the operator to view the Help text. The Page Up and Page Down keys on the PC Keyboard (↑ arrow and ↓ arrow keys on the Membrane Keypad) are used to view additional Help information, if there is more than one screen of text.

For more information see **Section 10:** ***Troubleshooting and Diagnostics*****, Subsection:** ***Diagnostics, Help/Error.***

Main

Press [MAIN] to return to the MAIN MENU.

Sample Analysis

An overview of sample analysis on the CELL-DYN 1700 System is provided in **Section 3: *Principles of Operation*, Subsection: *Sample Analysis Cycle Overview.*** This section provides guidelines and instructions for routine sample analysis.

There are two modes of operation in the CELL-DYN 1700 System: Open and Pre-Dilute. This subsection discusses the procedure for running samples in both these modes. Samples may be analyzed whenever READY is displayed in the Status Box on the **RUN** menu. Prior to running patient samples:

- Daily QC (Quality Control) checks should be performed.
- Samples should be well mixed.
- *If the system has been idle for fifteen minutes or more, a Normal Background should be run immediately prior to running a patient sample.*

Operator ID

The operator should enter an operator ID before running samples. The operator ID is displayed on all screens and printed on the graphics report and the ticket report. It is also retained in the QC Logs and the Data Log.

The operator ID is entered from the **MAIN MENU**. When this screen is selected, the cursor is positioned in the **<OPERATOR ID>** entry field. Type up to three digits. Press Enter to save the ID number if it is less than three digits.

Sample Identification

Sample identification information is entered in the upper left corner of the **RUN** menu. These entry fields are made available by pressing **[SPECIMEN TYPE]** followed by **[PATIENT SPECIMEN]**.

1. A specimen ID number of up to nine digits may be entered in the **<NEXT ID#>** entry field.

2. An Auto-Increment feature automatically increases the specimen ID number by one digit each time a sample is run. However, if the Auto-Increment feature has been selected, and the **<NEXT ID#>** field has been entered, and then a different Specimen Type is selected, then the Auto-Increment feature will be disengaged. Upon reentering the **PATIENT SPECIMEN RUN** menu, the **<NEXT ID#>** field *must* be reentered—even if the desired number is already displayed. Refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions.***

Alerts and Indicators

This subsection describes information displayed on the screen as the samples are analyzed and/or when reports are printed.

> **NOTE:** This subsection does not discuss how to interpret parameter flags, which are displayed after the sample is run. For detailed explanations of each flag, refer to **Section 3: *Principles of Operation,* Subsection: *Operational Messages and Data Flagging.***

- Results that fall outside the range of the Patient Limit set or Panic Limits are displayed in inverse video. These results are underlined on the graphics printout with an Out-of-Range Indicator. Results are preceded by an asterisk (*) on a preprinted ticket.
- Results that exceed the upper end of the parameter's Reportable Range are indicated by >>>> in place of the result.
- If a WBC or RBC/PLT Metering Fault occurs, results are suppressed for the affected parameters and the appropriate **CLOG** or **FLOW ERR** message is displayed. The upper metering and count times are also displayed. These messages and times are also printed in the graphics report.

> **NOTE:** A complete explanation of metering faults is given in **Section 3: *Principles of Operation,* Subsection: *Operational Messages and Data Flagging.***

- **[CLEAR ALARM]** is displayed and a message (for example, **Diluent Empty**) appears in the Status Box on the Data Module screen if a fault condition is detected.
- After the problem has been corrected, press **[CLEAR ALARM]** to resume operation.

Running Samples — Open Sample Mode

To run samples in the Open Sample Mode, follow the instructions below.

1. Be sure that READY is displayed in the Status Box on the **RUN** menu.
2. Mix the sample well, then open the sample tube. Place it under the Sample Aspiration Probe and raise the tube so that the end of the probe is deeply immersed in the sample.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling these samples. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

3. Press the Touch Plate to start the cycle. The Status Box on the **RUN** menu displays messages to indicate the various stages of the cycle.
4. Remove the sample tube after the probe has moved up through the Wash Block. The beep sounds upon initiation of probe cleaning.
5. When the cycle is complete, the probe moves down into position for the next sample and the results are displayed on the screen.
6. If Automatic Report Printing has been specified in the **SETUP** menu, a report is printed according to the parameters selected during the Setup Procedure.
7. If Automatic Report Printing has not been specified in the **SETUP** menu, press **[PRINT REPORT]** to obtain a copy of the results. The print report format is the only method to be used for reporting patient results.
8. Repeat this procedure for subsequent samples.

Running Samples — Pre-Dilute Mode

To run samples in the Pre-Dilute Mode, follow the instructions below.

1. Be sure that READY is displayed in the Status Box on the **RUN** screen.

2. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**. Press **[MORE]** twice.
3. Press **[10 mL DISPENSE]** to activate the Dispense Mode. (This key is now highlighted in dark blue.)
4. Hold a clean CELL-DYN Counting Cup under the Open Mode Sample Probe. Hold the cup at a slight angle so that the fluid dispensed from the probe flows down the side of the cup to the bottom — if the cup is held straight, the force of the dispensing fluid may cause fluid to splash out of the cup.

CAUTION: Allowing fluid to splash out of the cup may adversely affect results.

NOTE: Use only CELL-DYN Counting Cups. Using other cups may cause spurious results.

WARNING: **Potential Biohazard.** The probe is sharp and potentially contaminated with infectious material. Avoid any contact with the probe.

5. Press **[10 mL DISPENSE]**. 10 mL (milliliters) of diluent dispenses into the cup.
6. Obtain a 40-µL end-to-end micropipette (available from Abbott). Hold the micropipette near one end, so that both ends are visible. Insert the tip of the other end into either the calibrator or sample. Tilt the micropipette at an angle that will allow the blood to flow completely to the opposite end.

WARNING: **Potential Biohazard.** Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

7. Remove the micropipette from the sample and carefully roll the outside of the micropipette across a lint-free gauze slightly dampened with diluent to remove all excess blood. Gently wipe the outside of the micropipette, if necessary. Do not remove any of the sample from inside the micropipette while wiping the outside.

NOTE: The micropipette is calibrated to contain exactly 40 µL of sample. Check both ends of the micropipette to make sure that it is still completely full of blood after the outside has been wiped.

8. Drop the filled micropipette immediately into one of the Counting Cups containing 10 mL of diluent which were prepared in the preceding steps. Fold the cup once at the upper crease (with the micropipette still inside), grip in the middle of the fold, and invert a minimum of 15 to 20 times to thoroughly mix the blood and diluent (see the following figure). Mix until the fluid inside the capillary is the same color as the rest of the fluid. This initial 1:250 dilution is stable for 20 minutes and must be thoroughly remixed by inversion before pouring it into the Pre-Mixing Cup when the Pre-Dilute Mode is selected.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030 other equivalent biosafety procedures.

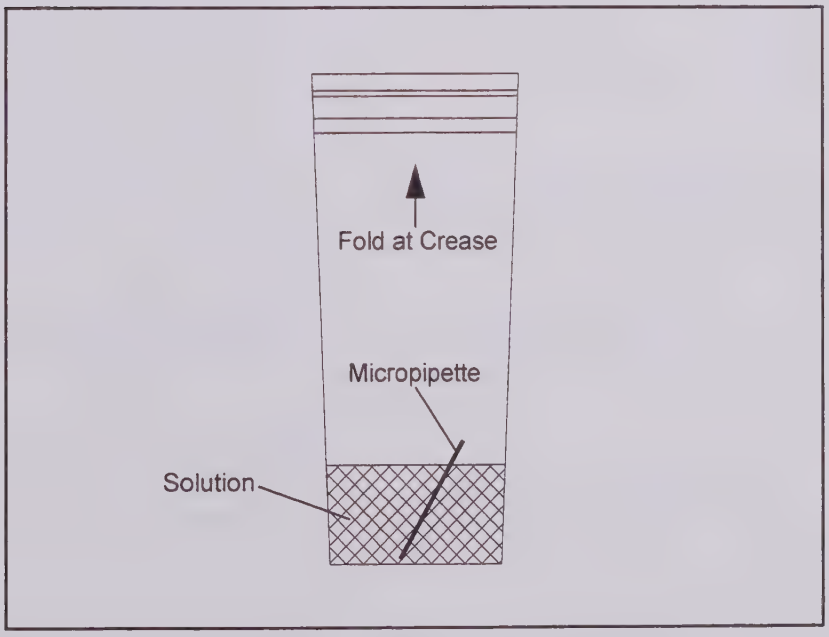

Figure 5.1: CELL-DYN Counting Cup with Micropipette

9. In the **RUN** menu, press **[PRE-DILUTE]** to activate the Pre-Dilute Mode. The Sample Probe is raised and positioned over the RBC/PLT Mixing Chamber, **PRE-DILUTE MODE** is displayed on the screen, and the **[PRE-DILUTE]** key is highlighted in dark blue indicating that the Pre-Dilute Mode has been activated.

10. Remove the Upper Front Cover. Refer to the instructions for removing the Upper Front Cover in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Flow Panel Inspection and Installation, Upper Front Cover Removal.***

⚠ **CAUTION:** To prevent damage to the Sample Probe, always confirm that the probe has been raised before attempting to remove the Upper Front Cover.

NOTE: The ground wire must be detached to completely remove the Upper Front Cover.

11. When READY appears on the screen, mix the Sample Cup by inverting it several times, and carefully pour the specimen into the Pre-Mixing Cup. (For the location of this cup, refer to Figure 1.3, Flow Panel — Open Mode View).

⚠ **CAUTION:** If the **[10 mL DISPENSE]** method was used, the micropipette is still inside the cup; be careful when pouring to prevent it from falling into the Pre-Mixing Cup.

⚠ **CAUTION:** If a pre-diluted solution is inadvertently poured into the Pre-Mixing Cup after the dilution is made but before leaving the **SPECIAL PROTOCOLS** menu, follow the instructions in ***Removing a Pre-Diluted Specimen from the Pre-Mixing Cup*** within this section. Otherwise the flow sequence of the instrument will be incorrect, resulting in overfilling of the WBC transducer and carryover of the pre-dilution into the next analysis.

12. Press the Touch Plate to start the Pre-Dilute cycle. The Status Box on the **RUN** menu displays messages to indicate the various stages of the cycle.

13. When the cycle is complete, the results are displayed on the screen.

14. If Automatic Report Printing has been specified in the **SETUP** menu, a report is printed according to the parameters selected during the setup procedure. If Automatic Report Printing has *not* been specified in the **SETUP** menu, press **[PRINT REPORT]** to obtain a copy of the results. The print report format is the only method to be used for reporting patient results.
15. When you have finished running samples in the Pre-Dilute Mode, reattach the Upper Front Cover. Be sure to reattach the ground wire.
16. To return to the Open Sample Mode, press **[PRE-DILUTE]**. The Sample Probe returns to the down position, **OPEN MODE** is displayed on the screen, and the **[PRE-DILUTE]** key is no longer highlighted.

Removing a Pre-Diluted Solution from the Pre-Mixing Cup

Pouring a pre-diluted solution into the Pre-Mixing Cup before leaving the **SPECIAL PROTOCOLS** menu will have several undesirable consequences. When the instrument is returned to the Pre-Dilute Mode, the pre-diluted solution will be transferred to the Mixing Chamber (and added to the rinse solution which is already in the chamber). As a result, the specimen/rinse mixture will contaminate the Mixing Chamber glassware above the level of the normal rinsing action, and may overflow into the two tubes (waste and vent) at the top of the Mixing Chamber. In addition, the mixture will not completely drain out of the Mixing Chamber at the end of the cycle, resulting in carryover to the next specimen dilution.

If a pre-diluted solution has been inadvertently poured into the Pre-Mixing Cup prior to returning to the **RUN** or **CALIBRATION** menu, perform the following steps:

1. In the **SPECIAL PROTOCOLS** menu, press **[MORE]** until **[DRAIN BATHS]** selection appears. Press **[DRAIN BATHS]**. When the drain cycle is finished, press **[FILL BATHS]**. This will leave clean diluent in the Mixing Chamber.
2. Return to the **10 mL Dispense** menu and perform the 10 mL Dispense Procedure to dispense 10 mL of clean diluent into a CELL-DYN Counting Cup (as instructed in the preceding section).
3. Pour the 10 mL of clean diluent into the Pre-Mixing Cup.
4. Press **[MORE]** until **[DRAIN BATHS]** selection is available again and repeat the **[DRAIN BATHS]** and **[FILL BATHS]** cycles.

5. Return to the **MAIN MENU** and select the **RUN** menu.
6. If necessary, leave the Pre-Dilute Mode. Press **[NORMAL BACKGROUND]**, and verify that the background counts are within the acceptable limits.
7. Continue with the instructions for running in the Pre-Dilute Mode.

Using the Data Log

The Data Log stores all data in a log format (including numeric and graphics data) for the last 5,000 cycles run on the instrument. The information is stored chronologically by sequence number (0 through 4999).

Each screen display (page) may contain up to 16 specimens. To view the previous page, use the Page Up key. To view the next page, use the Page Down key. Use the ← arrow and → arrow keys to scroll through the complete list of parameters for all specimens displayed on a page.

Data Log Menu

When [DATA LOG] is pressed, the DATA LOG menu is displayed and the following keys are available:

[EDIT ID]
[DISPLAY SPECIMEN]
[FIND SPECIMEN]
[REJECT/ACCEPT FROM X-B]
[TRANSMIT DATA]
[PRINT DATALOG]
[HELP/ERROR]
[MAIN]

Edit ID

[EDIT ID] is used to change the number of a specific specimen ID among those displayed on the DATA LOG menu. When the cursor is positioned on a patient specimen, this key is displayed; otherwise it is blank. After a new specimen ID number has been typed in, press Enter to accept the entry. Press the ESC key or asterisk (*) key to cancel the entry.

Display Specimen

[DISPLAY SPECIMEN] is used to display the record of the specific specimen indicated by the position of the cursor. When this key is pressed, the DISPLAY SPECIMEN menu is displayed and the following keys are available:

[PREVIOUS SPECIMEN]
[NEXT SPECIMEN]
[EDIT DEMOGRAPH]
[TRANSMIT SPECIMEN]
[PRINT TICKET]
[PRINT REPORT]
[HELP/ERROR]
[RETURN]

[PREVIOUS SPECIMEN] is used to display the previous specimen in the Data Log.

[NEXT SPECIMEN] is used to display the next specimen in the Data Log.

[EDIT DEMOGRAPH] is used to edit the patient demographics section of Patient Specimens only (this key does not appear for other specimen types). Press [CONFIRM EDIT] to save the changes. Press [CANCEL EDIT] to cancel this function.

[TRANSMIT SPECIMEN] is used to transmit the specimen results to a Laboratory Information System (LIS).

[PRINT TICKET] is used to print the specimen results on a preprinted ticket.

[PRINT REPORT] is used to print the specimen results on a graphics printout.

Find Specimen

[FIND SPECIMEN] is used to find a specimen using the sequence number, specimen ID number, or patient name from the DATA LOG menu. When [FIND SPECIMEN] is pressed, three entries appear in the upper left corner of the screen — <SEQUENCE #>, <NEXT ID#>, and <NAME> — and the cursor is positioned in the <SEQUENCE #> field. The operator can place the cursor in the <NEXT ID#> field or <NAME> field using the arrow keys.

Reject from X-B / Accept to X-B

The operator can toggle between the [REJECT] and [ACCEPT] keys to either exclude or include specimens in the X-B Analysis.

NOTE: Only specimens that were initially included in the X-B Analysis, indicated by a "B" to the left of the sequence number, can be rejected and reaccepted using the [REJECT] and [ACCEPT] keys. When the cursor is placed on one of these specimens, either the [REJECT] key or [ACCEPT] key is displayed. When the cursor is placed on a specimen that was not initially included in the X-B Analysis, neither key is displayed.

To include specimens in the X-B Analysis, use the Enter key to turn ON the X-B Moving Average Program in the main SETUP menu before running samples.

- To reject the results of a specific sample, move the cursor to the sequence number of that sample and press [REJECT FROM X-B]. The "B" to the left of the sequence number is deleted and an "R" is displayed to the right of the specimen ID number.
- To reaccept the results of a specimen previously rejected, press [ACCEPT TO X-B]. The "R" is deleted and a "B" reappears to the left of the sequence number.

Transmit Data

[TRANSMIT DATA] is used to transmit one or more specimen records in the Data Log to a Laboratory Information System (LIS). Records may be transmitted singly or in batches as designated by the sequence numbers.

When [TRANSMIT DATA] is pressed, the <Starting Sequence #> field appears in the upper left corner of the screen and the cursor is positioned in this field. The operator should enter the sequence number of the first specimen to be transmitted. If the number is valid, the system accepts the entry and the <End Sequence #> field appears in the upper left corner of the screen. The operator should type in the ending sequence number. If you are transmitting only one specimen, the system begins transmitting automatically. If you are transmitting more than one specimen, press [CONFIRM TRANSMIT] or [CANCEL TRANSMIT]. If you press [CONFIRM TRANSMIT] the system begins transmitting the list of records to the host computer.

NOTE: Use the ESC key or asterisk (*) to cancel this function and return to the DATA LOG menu. Use the Backspace key or left arrow key to cancel an entry and retype the sequence number.

Because specimen records are shown in summary form on the DATA LOG menu, only the summary data of these records will be transmitted. No histogram data accompanies the summary data. To transmit histogram data, the Automatic Transmission of Histograms option in the Computer Setup submenu of the SETUP menu must be turned ON (refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions),*** and the operator must first press [DISPLAY SPECIMEN] to select and display an individual specimen, then press [TRANSMIT SPECIMEN].

Print Datalog

[PRINT DATALOG] is used to print one or more specimen records in the Data Log. When [PRINT DATALOG] is pressed, the <STARTING SEQUENCE #> field appears in the upper left corner of the screen and the cursor is positioned in this field. The operator should enter the sequence number of the first specimen to be printed. If the number is valid, the system accepts the entry and <ENDING SEQUENCE #> field appears in the upper left corner of the screen. The operator should type in the ending sequence number.

> NOTE: Use the ESC key or asterisk (*) to cancel this function and return to the DATA LOG menu. Use the Backspace key or left arrow key to cancel an entry and retype the sequence number.

Because specimen records are shown in summary form on the DATA LOG menu, only the summary data of these records will be printed. No histogram data accompanies the summary data. To print histogram data, the Print Histograms option in the SETUP menu must be turned ON (refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions***), and the operator must first press [DISPLAY SPECIMEN] to select and display an individual specimen, then press [PRINT REPORT].

Daily Shutdown

It is not necessary to manually shut down the instrument each day, since the instrument automatically goes into STANDBY if it has been idle for four hours or some other duration specified by the operator using the Auto Shutdown option (refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions***). If desired, the operator may place the instrument in the STANDBY mode by pressing [DAILY SHUTDOWN] in the SPECIAL PROTOCOLS menu. This causes the equipment to:

1. Rinse the Flow System.
2. Set the timer control that periodically opens all of the solenoid valves, which are closed in the STANDBY state, to prevent pinched tubing.

NOTES

Power Off

When the power is required to be OFF, the operator must perform the same procedures described in ***Daily Shutdown*** within this section.

1. Press [DAILY SHUTDOWN] in the SPECIAL PROTOCOLS menu.
2. When the cycle is complete, turn the Right Side Panel Power Switch to OFF.
3. To restore power, follow the procedures described in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Power On***.

NOTES

References

1. National Committee for Clinical Laboratory Standards. *Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture—Third Edition.* Approved Standard. NCCLS Document H3-A3. Villanova, PA. 1991.

2. National Committee for Clinical Laboratory Standards. *Procedure for the Collection of Diagnostic Blood Specimens by Skin Puncture—Third Edition.* Approved Standard. NCCLS Document H4-A3. Villanova, PA. 1991.

NOTES

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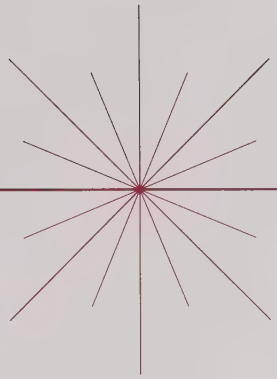
CELL-DYN® 1700 SYSTEM



Calibration Procedures

Calibration Procedures

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Overview

The CELL-DYN® 1700 System is calibrated at the factory prior to shipment. An Abbott-authorized Field Service Representative will assist the operator in confirming the calibration during instrument installation. Calibration may be performed using commercial calibrator or fresh whole blood. Only the directly measured parameters — WBC, RBC, HGB, MCV, PLT, and MPV — may be calibrated.

The instrument is electronically stable and should not require frequent recalibration when it is operated and maintained according to the recommendations in this manual. Built-in Quality Control programs are designed to provide continual monitoring and confirmation of instrument calibration. The laboratory should make the decision to recalibrate based on the performance of the CELL-DYN 1700 System in these Quality Control programs. The programs include statistical computations and modified Westgard Rules for commercial or patient controls and monitoring of patient samples for RBC parameters using Bull's Moving Average Program (X-B).

Calibration should be confirmed on a regular basis according to the requirements governing Quality Control in your laboratory. In keeping with good laboratory practices, this should include daily confirmation on each shift and following a reagent lot number change. Confirmation of calibration is also recommended following the replacement of any major instrument component that could affect calibration. Calibration may be confirmed by running appropriate commercial controls or by using fresh whole blood samples that were analyzed on a reliably calibrated hematology analyzer or by reference methodology.

NOTES

Calibration Guidelines

General Information

The CELL-DYN 1700 System analyzes two types of samples:

- Whole blood samples
- Pre-diluted samples

When processing whole blood samples, the operator is able to run specimens in either the Open Sample Mode or Closed Sample Mode. In the Open Sample Mode, the operator holds an open collection tube under the Open Mode Sample Probe that aspirates the sample. For a description of the aspiration procedures for the Closed Sample Mode, refer to **Section 13: *CELL-DYN 1700 CS — Closed Sample Aspiration.***

When processing pre-diluted samples, the operator uses only the Open Sample Mode. The Pre-Dilute Method is discussed later in this section.

There are two ways to accomplish the total calibration of the instrument — Auto-Cal and Enter Factor — depending on the preference of the user.

Calibration Procedural Guidelines

The two total calibration methods of the instrument are:

1. Auto-Cal — an automatic calibration program incorporated in the software. There are three methods under Auto-Cal:
   - Calibrator
   - Fresh Whole Blood
   - MPV Latex (performed by authorized Abbott representatives only)

2. Enter Factor — an alternative to Auto-Cal that allows the operator to manually enter calibration factors. The Enter Factor Method may be preferred when calibrating with whole blood samples.

The instrument's Open Sample Mode is calibrated with the calibration material of choice (calibrator or whole blood), using either Auto-Cal or Enter Factor. This section gives a detailed explanation of how to perform each procedure. Before beginning the selected calibration procedure, review ***Pre-Calibration Procedures*** later in this section.

The calibration procedures have been divided into subsections that consist of a series of easy-to-follow steps. Always follow the entire procedure.

For the Enter Factor Method of calibration, the worksheets provided at the end of this section may be used to assist in making the necessary calculations. These worksheets may be duplicated as needed.

Calibration Materials

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling these samples. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Two calibration materials can be used to calibrate the CELL-DYN 1700 System:

- CELL-DYN calibrator. The term "calibrator" refers to a commercial reference material. A calibrator is the preferred material for calibrating the CELL-DYN 1700 System. The most efficient way to calibrate the Open Sample Mode of the CELL-DYN 1700 System is to use calibrator material and the Auto-Cal Method.

  NOTE: According to CLIA '88 (Clinical Laboratory Improvement Act of 1988), when a control is used as a calibrator, a different lot or brand of control must be used for Daily Quality Control.

  Never use a hemoglobin standard that is designed specifically for use with cyanmethemoglobin reagents.

- Fresh whole blood. Blood samples should be from the general patient population, be less than four hours old when calibration begins, and not exceed eight hours by the time calibration is completed. For additional whole blood requirements, see ***Fresh Whole Blood Sample Requirements*** within this section.

Fresh Whole Blood Sample Requirements

The International Committee for Standardization in Hematology (ICSH) defines a fresh blood sample as one available for processing less than four hours following venous sampling.

- All blood samples should be less than four hours old when calibration begins, and less than eight hours old by the time calibration is completed.
- Blood samples should be from the general patient population, with values for all parameters which are within the laboratory's normal range.
- All samples must be properly collected in the EDTA anticoagulant used by the laboratory.
- Each tube should contain at least 90% of the nominal collection volume of blood.
- All cellular morphology must be normal.
- No known interfering substances should be present (for example, lipemia, icterus, drugs).
- Samples should be at room temperature and mixed properly.

NOTES

Calibration Methods

Overview

The methodology for calibrating the CELL-DYN 1700 System using Auto-Cal and Enter Factor is discussed in this subsection.

Calibration Menu

In the **MAIN MENU**, press **[CALIBRATION]** to display the **CALIBRATION** menu. The system defaults to the Whole Blood Open Sample Factors screen. A brief description of each soft key, displayed at the bottom of the **CALIBRATION** menu, and its function is given below.

Pre-Dilute

[PRE-DILUTE] is used to prepare the instrument for analyzing pre-diluted samples by raising the Open Mode Sample Probe to allow the operator to remove the Upper Front Cover from the instrument and pour a diluted sample of calibrator or fresh whole blood into the Pre-Mixing Cup.

Auto-Cal Select

[AUTO-CAL SELECT] is used to display the **AUTO-CAL** menu, allowing the operator to choose a method for calibration of the instrument. (The operator may choose Calibrator or Whole Blood. The **[MPV LATEX]** key is used only by an authorized Abbott representative.)

Enter Factor

[ENTER FACTOR] is used to display a new screen and allows the operator to enter calibration factors for each of the five displayed parameters in the Open, Closed, or Pre-Dilute modes.

Print

[PRINT] is used to print the current calibration factors, as shown on the screen, to the Graphics Printer.

NOTES

Pre-Calibration Procedures

It is advisable to perform calibration at a time when it can be completed without interruption. The Pre-Calibration Procedures in this subsection help ensure proper instrument performance and a successful calibration. These steps must be completed just before starting the calibration process. If problems are detected during these checks, *do not attempt to calibrate the instrument.* If necessary, call the Abbott Customer Support Center for assistance. After the problems have been resolved, repeat the Pre-Calibration Procedures to verify proper performance. Review the following guidelines before beginning any calibration procedure.

- Use only the recommended CELL-DYN Reagents (refer to **Section 1:** ***Use or Function,*** **Subsection:** ***System Components, Reagent System).***
- Confirm that reagent containers are at least one third full — replace them as necessary.
- Confirm that the waste container is no more than half full — empty it if necessary as described in **Section 8:** ***Hazards,*** **Subsection:** ***Handling Waste and Waste Containers.***
- Prior to calibration, verify that instrument precision is within the stated Within Sample Limits. (For calibration, refer to Table 4.7, Within Sample Precision of the Hemogram Parameters — Open Mode.)
- Always ensure that daily, weekly, and monthly scheduled maintenance (as described in **Section 9:** ***Service and Maintenance***) is current before calibrating the instrument. Instrument cleanliness is essential for accurate calibration. Therefore, each laboratory should perform any additional maintenance according to its requirements.
- Confirm that Normal Background is within limits. If the system has been idle for fifteen minutes or more, a Normal Background should be run immediately prior to running any calibration specimens.
- Confirm that the Operator ID number is entered.

NOTES

Open Mode Calibration

Auto-Cal Method

Overview

The software that accompanies the CELL-DYN 1700 System allows the operator to automatically calibrate the instrument using the Calibrator or Whole Blood Method. This subsection describes how the instrument is calibrated using each of these methods. The Calibrator and Whole Blood Methods allow the operator to enter reference assay values, run samples, and compare the results with the entered assay values. The computer utilizes the results from a minimum of three runs from the same sample to calculate a factor for each parameter selected for calibration. A Mean Factor for each selected parameter, based on the total number of runs from all specimens, is also calculated. With the Calibrator Method, one sample is used for calibration. With the Fresh Whole Blood Method, multiple samples are used.

Auto-Cal Ranges for Calibrator and Fresh Whole Blood

The following ranges are programmed for the reference values that may be entered in the Auto-Cal program. Values exceeding these limits cannot be entered.

Parameter	Lower Limit	Upper Limit
WBC	5.0	15.0
RBC	3.50	6.00
HGB	4.0	24.0
MCV	80	100
HCT*	28.0	60.0
PLT	150	450

*When the RBC and HCT values are entered, a reference value for MCV is automatically calculated.

Auto-Cal Procedure — Calibrator

1. In the **MAIN MENU**, press **[CALIBRATION]** to display the **CALIBRATION** menu. The system defaults to the Current Whole Blood Open Sample Factors screen. Press **[AUTO-CAL SELECT]** to display the **AUTO CALIBRATION** submenu. Press **[PRINT]** to print the current Calibration Factors.
2. Press **[CALIBRATOR]** to display the **CALIBRATOR CALIBRATION** menu.
3. Use the arrow keys to place the cursor on the first parameter to be calibrated. Use the Enter key to toggle between YES and NO to select the parameters for calibration. When YES is displayed next to the parameter, the cursor is positioned in the value field for that parameter.
4. For each parameter to be calibrated, enter the corresponding reference assay value from the sheet enclosed with the calibrator material. As each value is entered, the field accepts the value and the cursor automatically moves to the next parameter. Use the arrow keys to skip a parameter.

   NOTE: When MCV is selected, the message **The reference value for MCV may be supplied by entering values for RBC and HCT. To do so, press # and enter values when prompted** appears in the lower part of the screen. When the pound (#) key is pressed, MCV changes to RBC, allowing the operator to enter the Red Blood Cells Reference Value (using three digits). Then **<HCT>** appears, allowing the operator to enter the Hematocrit Reference Value. The computer-calculated MCV Reference Value must be within the normal range of 80 to 100 to be accepted and displayed.

5. Prepare the calibrator for use according to the directions given in the package insert. Be certain to carefully read and follow directions given for warming and mixing.

WARNING: Potential Biohazard. Consider all specimens potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

6. When READY appears on the screen, place the well-mixed calibrator specimen under the Open Mode Sample Probe and press the Touch Plate to activate the Auto-Calibration cycle. The Analyzer performs RUN 1 and displays the values in the RUN 1 column. Repeat this step for RUN 2 and RUN 3 measurements, mixing the calibrator material well between runs.

WARNING: Potential Biohazard. The probe is sharp and potentially contaminated with infectious material. Avoid any contact with the probe.

NOTE: If the RUN results are highlighted and the Calibration Factor has not been calculated for that parameter, the instrument has failed the Reference Check. The Auto-Cal program automatically compares the results of the first run of the calibrator with the parameter Reference Values entered for that sample to verify that the difference is within acceptable limits. See ***Calibration Troubleshooting*** within this section.

7. After three "good" runs, the Factor and Mean Factor for each parameter to be calibrated are calculated by the system.

   NOTE: If after three runs the Factor and Mean Factor have not been calibrated, the following conditions may exist:

   > < is displayed in the Factor column and a Mean Factor will not be calculated and displayed, if the instrument fails the Precision Check. After three "good" runs, the instrument performs a Precision Check for each parameter being calibrated before determining the Factor and Mean Factor for that parameter. See ***Calibration Troubleshooting*** within this section.

   >>> or <<< is displayed in the Factor column and a Mean Factor is not calculated if the instrument fails the Allowable Limits used for calculating the Mean Factor.

8. Press **[RETURN]** to save the Calibration Factors.
9. Press **[PRINT]** to print a copy of the New Calibration Factors.
10. Press **[RETURN]** to return to the **CALIBRATION** menu.
11. Press **[MAIN]** to return to the **MAIN MENU**.
12. Press **[RUN]** to display the **RUN** menu.

13. Run three levels of controls and confirm that the results obtained for all parameters are within the control limits specified on the assay sheet or within your own established laboratory ranges for the current lot number.

Auto-Cal Procedure — Fresh Whole Blood

Calibration with fresh whole blood samples is an alternative to calibration with a commercial calibrator. This subsection explains the method of calibrating with fresh whole blood samples.

General Guidelines — Fresh Whole Blood

Samples are first run on a reference instrument. The mean values derived from these samples are noted and input into the CELL-DYN 1700 System to be calibrated. The same whole blood samples are then run on the instrument to be calibrated.

Reference values for Whole Blood Calibration should be determined according to the following ICSH (International Committee for Standardization in Hematology) recommendations.

WBC, RBC, and PLT

Reference values may be determined using multiple counts from a certified hemocytometer or from a reliably calibrated hematology analyzer.

Hemoglobin

Reference values may be determined using either the Reference Cyanmethemoglobin Method or a reliably calibrated hemoglobinometer or hematology analyzer.

> NOTE: DO NOT attempt to calibrate the CELL-DYN 1700 System with a *hemoglobin standard* designed for the calibration of specific Reference Cyanmethemoglobin Methods. The instrument uses a Modified Hemoglobincyanide Method which is not designed to analyze these standards directly.

MCV

Hematocrit Reference Values may be determined from the Reference Microhematocrit. RBC Reference Values may be determined by using multiple counts from a certified hemocytometer or from a reliably calibrated hematology analyzer. The MCV can be calculated from the Reference HCT and RBC Values.

> **NOTE:** Reference Microhematocrit Values may be determined by multiple analyses using the NCCLS Method for Packed Cell Volume (PCV). Use only plain (non-anticoagulated) capillary tubes. Be certain to verify the proper operation of the microhematocrit centrifuge and the timer as recommended by NCCLS (National Committee for Clinical Laboratory Samples).

Requirements for Fresh Whole Blood — Auto-Cal

Minimum requirements for Whole Blood Calibration are described in the following list. Additional samples and/or more replications of the samples may be used. For additional requirements, see ***Calibration Guidelines, Fresh Whole Blood Sample Requirements*** within this section.

- A minimum of five samples is required for adequate Whole Blood Calibration.
- Samples must be assayed at least in triplicate by reference methodology and on the CELL-DYN 1700 System.
- No more than two hours should elapse between the CELL-DYN 1700 run and the assay by reference methodology.
- For each sample run on the reference instrument, a Reference Mean Value should be calculated for each parameter to be calibrated. These mean values can then be entered in the Auto-Cal program as Reference Mean Values for the Calibration process.

Determining Reference Values — Fresh Whole Blood

Use the following procedure to determine the Reference Mean Values that will be used in the Calibration Procedure for Auto-Calibration with fresh whole blood.

1. Go to a reference hematology instrument or use the appropriate hematology method with five samples of fresh whole blood. Label the five samples #1 through #5. Run a minimum of three replicates from sample #1 and calculate a mean for each parameter to be calibrated. Be sure the means derived from each of the remaining samples are clearly identified.
2. Repeat this procedure for each of the remaining four samples.
3. The Reference Mean Values obtained on the reference hematology instrument or hematology methods will be used to calibrate your CELL-DYN 1700 System. The same blood samples run on the reference hematology instrument will be run on the CELL-DYN 1700 System to be calibrated.

Performing Auto-Cal Calibration — Fresh Whole Blood

1. Go to the CELL-DYN 1700 System to be calibrated. In the **MAIN MENU**, press **[CALIBRATION]** to display the **CALIBRATION** menu. The system defaults to the Current Whole Blood Sample Factors screen. Press **[AUTO-CAL SELECT]** to display the **AUTO CALIBRATION** menu. Press **[PRINT]** to print the current Calibration Factors.
2. Press **[WHOLE BLOOD]** to display the **WHOLE-BLOOD CALIBRATION** menu.
3. Use the arrow keys to place the cursor on the first parameter to be calibrated. Use the Enter key to toggle between YES and NO to select the parameters for calibration. When YES is displayed next to the parameter, the cursor is positioned in the value field for that parameter.
4. Select sample #1 that was run on the reference instrument. Using the Reference Mean Value derived from the reference instrument, enter the corresponding mean for each parameter to be calibrated. As each value is entered, the field accepts the value and the cursor automatically moves to the next parameter. Use the arrow keys to skip a parameter.

NOTE: When entering a Reference Mean Value for MCV, the Value field on the Calibration screen accepts only a two-digit number. Therefore, when entering an MCV Reference Mean Value from the replicate file mean, it will be necessary to follow these instructions:

- A digit to be rounded is not changed if it is followed by a digit less than five.

  Example: 86.4 would be rounded to 86

- If the digit to be rounded is followed by a digit greater than five or by five followed by other nonzero digits, it is increased by one.

  Example: 86.6 would be rounded to 87
  86.54 would be rounded to 87

- When the digit to be rounded is followed by five it is unchanged if it is even but increased by one if it is odd.

  Example: 86.5 would be rounded to 86
  87.5 would be rounded to 88

- All values within the same calculation should be carried out to the same decimal place.

NOTE: When MCV is selected, the message **The reference value for MCV may be supplied by entering values for RBC and HCT. To do so, press # and enter values when prompted** appears in the lower part of the screen. When the pound (#) key is pressed, MCV changes to RBC, allowing the operator to enter the Red Blood Cells Reference Value (using three digits). Then **<HCT>** appears, allowing the operator to enter the Hematocrit Reference Value. The computer-calculated MCV Reference Value must be within the normal range of 80 to 100 to be accepted and displayed.

5. Mix the sample well by inverting it at least ten times. Do not shake the specimen.

WARNING: Potential Biohazard. Consider all specimens potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

6. When READY appears on the screen, place the well-mixed reference whole blood specimen under the Open Mode Sample Probe and press the Touch Plate to activate the Auto-Calibration cycle. The Analyzer performs RUN 1 and displays the values in the RUN 1 column. Repeat this step for RUN 2 and RUN 3, mixing the whole blood specimen between runs. The Whole Blood Method requires three "good" runs to automatically calculate the Factor and Mean Factor for those parameters selected for calibration.

   NOTE: The Auto-Cal Program automatically compares the results of the first run of the whole blood specimen with the parameter Reference Mean Values entered for that sample to verify that the difference is within acceptable limits. If any of the runs fails this Reference Check, the results are highlighted and no calibration factor will be calculated for that parameter. See ***Calibration Troubleshooting*** within this section.

7. After three "good" runs, the Factor and Mean Factor for each parameter to be calibrated are calculated by the system.

   NOTE: If after three runs the Factor and Mean Factor have not been calibrated, it may be due to one of the following conditions:

   > < is displayed in the Factor column and a Mean Factor will not be calculated and displayed, if the instrument fails the Precision Check. After three "good" runs, the instrument performs a Precision Check for each parameter being calibrated before determining the Factor and Mean Factor for that parameter. See ***Calibration Troubleshooting*** within this section.

   >>> or <<< is displayed in the Factor column and a Mean Factor is not calculated if the instrument fails the Allowable Limits used for calculating the Mean Factor.

8. Repeat steps 4 through 6 four more times for the remaining four reference samples. Enter the new Reference Mean Values that correspond to each of the remaining four reference samples before running the specimens: for example, enter the Reference Mean Values for sample #2, then run sample #2, etc. A new Factor for each parameter to be calibrated will be calculated each time three runs are completed for a sample. The Mean Factor for each parameter will be based on the total number of runs. When all five samples have been run in triplicate (15 runs), the instrument is calibrated.

9. Press [RETURN] to save the Calibration Factors.
10. Press [PRINT] to print a copy of the New Calibration Factors.
11. Press [RETURN] to return to the CALIBRATION menu.
12. Press [MAIN] to return to the MAIN MENU.
13. Press [RUN] to display the RUN menu.
14. Run three levels of controls and confirm that the results obtained for all parameters are within control limits specified on the assay sheet or within your own established laboratory ranges for the current lot number.

    NOTE: If the results for any parameter are consistently out, repeat calibration or obtain technical assistance by contacting the Abbott Customer Support Center.

Enter Factor Method — Calibrator or Fresh Whole Blood

Overview

The Enter Factor Calibration Method is used to enter a predetermined factor to adjust calibration when a consistent bias exists between the CELL-DYN 1700 System and a comparison analyzer. A percent Bias Factor can be determined and entered to change calibration within ± 20% for any of the directly measured parameters — WBC, RBC, HGB, MCV, PLT, MPV. A set of worksheets is provided at the end of this section that can be used for Whole Blood Enter Factor Calibration.

Determining Reference Values — Calibrator or Fresh Whole Blood

Use the following procedure to determine the reference values that will be used in the calibration procedure for Enter Factor with fresh whole blood or calibrator material. No more than two hours should elapse between determining the Reference Mean Values and performing the calibration.

1. If calibrator material is used, skip directly to step 1 of ***Enter Factor Calibration Procedure — Calibrator or Fresh Whole Blood***.
2. If fresh whole blood is used, go to a reference hematology instrument or use appropriate hematology methods with five samples of fresh whole blood. Label the five samples #1 through #5. Run a minimum of three replicates from each of the five samples on the reference instrument for a total of 15 runs. It is not necessary to calculate a mean for each sample.

3. If a mean value for each parameter based on 15 runs is not automatically calculated by the reference hematology instrument or hematology methods, use a calculator to determine the cumulative Reference Mean for each parameter. For example:

   The cumulative Reference WBC Mean is 7.10 when all of the following are true:

   - Specimen #1: RUN 1 = 6.8, RUN 2 = 6.9, RUN 3 = 6.2
   - Specimen #2: RUN 1 = 8.2, RUN 2 = 8.9, RUN 3 = 8.5
   - Specimen #3: RUN 1 = 5.9, RUN 2 = 5.5, RUN 3 = 6.2
   - Specimen #4: RUN 1 = 7.6, RUN 2 = 7.8, RUN 3 = 7.4
   - Specimen #5: RUN 1 = 6.9, RUN 2 = 6.7, RUN 3 = 7.0

   The cumulative mean of 7.10 equals the sum of the values (106.5) divided by the 15 runs.

Enter Factor Calibration Procedure — Calibrator or Fresh Whole Blood

1. Go to the CELL-DYN 1700 System to be calibrated. Open an empty replicate file. Follow the instructions for opening replicate files described in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions, SETUP Screen Options, QC Setup Key, Replicate File Setup.***
2. If calibrator material is used, follow the mixing instructions found in the package insert. Do not shake the specimen. If fresh whole blood is used, take sample #1 and mix it well by inverting it at least ten times. Do not shake the specimen.
3. If calibrator material is used, when READY appears in the Status Box, place the calibrator under the Open Mode Sample Probe and press the Touch Plate to run the specimen. The results of the run are placed in the replicate file selected in step 1. Repeat this step two more times for a total of three runs in the replicate file. Go to step 4.

   If fresh whole blood is used, when READY appears in the Status Box place sample #1 under the Open Mode Sample Probe and press the Touch Plate to run the specimen. The results of the run are placed in the replicate file selected in step 1. Run this specimen two more times. Repeat this triplicate run for each of the remaining four specimens, for a total of 15 runs. Run all specimens in the same replicate file to obtain a CELL-DYN Mean for all parameters.

WARNING: **Potential Biohazard.** Consider all specimens potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

4. Press **[MAIN]**. Press **[QUALITY CONTROL]**, followed by **[REPLICATES]**, and select the appropriate replicate file.
5. Press **[VIEW QC LOG]** and press **[PRINT QC LOG]** to print the Summary Report for the selected replicate file. Return to **MAIN MENU**.
6. Press **[CALIBRATION]** to display the Whole Blood Open Sample Factors screen. Press **[PRINT]** to obtain a copy of the Current Open Mode Calibration Factors that will be used in determining the new Calibration Factors.
7. To determine the New Calibration Factor:

   Use the Reference Mean Values determined in ***Open Mode Calibration, Enter Factor Method, Determining Reference Values — Calibrator or Fresh Whole Blood*** and the CELL-DYN Mean values determined in steps 2 through 5. Enter this information in the Enter Factor Open Sample Mode Whole Blood Calibration Worksheet provided at the end of this section to calculate the new Open Mode Calibration Factor for each parameter as follows:

   Calibrator Calibration:

   $$\frac{\text{Calibrator Mean}}{\text{CELL-DYN Mean}} \times \text{Current Open Mode Calibration Factor} = \text{New Open Mode Calibration Factor}$$

   Whole Blood Calibration:

   $$\frac{\text{Reference Mean}}{\text{CELL-DYN Mean}} \times \text{Current Open Mode Calibration Factor} = \text{New Open Mode Calibration Factor}$$

   For example, if the Reference Mean Value for WBC is 6.6, the CELL-DYN Mean for WBC is 7.1, and the current Open Mode Calibration Factor is 0.98, then:

   $$(6.6 / 7.1) \times 0.98 = 0.91$$

   and 0.91 is your New Open Mode Calibration Factor.
8. With the **CALIBRATION** menu displayed, press **[ENTER FACTOR]**.

9. Use the arrow keys to select the first factor to be changed. Enter the three-digit New Calibration Factor calculated from step 7. The cursor automatically advances to the next factor. Use the arrow keys to select a parameter.

   NOTE: **[RESTORE FACTORS]** is used to recall factors, stored on the Hard Disk, corresponding to the current mode — Open, Closed, or Pre-Dilute. **[RESET ALL TO 1.00]** is used to reset all factors displayed on the screen to 1.00.

10. Press **[RETURN]** to save the calibration factors.

11. Press **[PRINT]** to print a copy of the New Calibration Factors.

12. Press **[MAIN]** to return to the **MAIN MENU**.

13. Confirm calibration of the CELL-DYN 1700 System by the following method:

    Run three levels of controls and confirm that the results obtained for all parameters are within the control limits specified on the assay sheet or within your own established laboratory ranges for the current lot number.

    NOTE: If the results for any parameter are consistently out, repeat calibration or obtain technical assistance by contacting the Abbott Customer Support Center.

Pre-Dilute Mode Calibration

Overview

The Pre-Dilute Calibration Method prepares the CELL-DYN 1700 System to accurately measure pre-diluted samples. Read all instructions carefully before using the Pre-Dilute Method. The procedure for calibrating the Pre-Dilute Mode and the type of specimens used are similar to the Calibrator and Fresh Whole Blood Methods described earlier in this section. However, for Pre-Dilute Calibration each calibration specimen is pre-diluted in the same manner as unknown patient specimens, using one of the following two methods:

1. Automated Pre-Dilute Method with CELL-DYN Counting Cups using the **[1/250 DILUTION]** key from the **SPECIAL PROTOCOLS** menu.

   NOTE: Do not use the **[1/250 DILUTION]** Method to calibrate the instrument unless you also intend to use the **[1/250 DILUTION]** Method to run pre-diluted patient samples.

2. Manual Method with 40-µL (microliter) CELL-DYN Micropipettes and CELL-DYN Counting Cups using the **[10 mL DISPENSE]** key from the **SPECIAL PROTOCOLS** menu

   NOTE: Use only CELL-DYN Counting Cups. Using other cups may cause spurious results.

Each of these methods is discussed in this subsection.

Determining Reference Values — Pre-Dilute

For specific material requirements used in the calibration process, refer to ***Fresh Whole Blood Sample Requirements*** and ***Auto-Cal Ranges for Calibrator and Fresh Whole Blood*** earlier in this section.

There are two methods for determining reference values before calibrating the Pre-Dilute Mode:

1. Calibrator
   Use the appropriate three-digit reference assay values from the sheet enclosed with the calibrator material.

2. Fresh Whole Blood
   Run five samples of fresh whole blood on a reference instrument. Your Open Mode calibrated CELL-DYN 1700 System may be used as the reference instrument to obtain reference values. If you use your CELL-DYN 1700 System as your reference instrument, you must calibrate the Open Mode using either calibrator or fresh whole blood before calibrating the Pre-Dilute Mode.

Use the following procedure to determine the reference values that will be used in the calibration procedure for the Pre-Dilute Mode. Use the same samples run on the reference instrument to prepare pre-diluted solutions, using either the **[1/250 DILUTION]** Method or the **[10 mL DISPENSE]** Method.

Auto-Cal Calibration Procedure

1. Go to a reference instrument or to the appropriate hematology method with five samples of fresh whole blood. Label the five samples #1 through #5. Run a minimum of three replicates from sample #1 and calculate a mean for each parameter to be calibrated. Be sure the means derived from each of the remaining samples are clearly identified for that sample.
2. Repeat this procedure for each of the remaining four samples.
3. The mean values obtained on the reference instrument or hematology methods will be used in the calibration process of your CELL-DYN 1700 System. The same blood samples run on the calibrated hematology instrument will be run on the CELL-DYN 1700 System to be calibrated.

Enter Factor Calibration Procedure

1. Go to a reference instrument or to the appropriate hematology method with five samples of fresh whole blood. Label the five samples #1 through #5. Run three replicates from each of the five samples (in the order numbered on the tube).
2. Calculate the mean for all fifteen values for each parameter to be calibrated.

3. The mean value for all fifteen runs for each parameter obtained on the reference instrument or hematology methods will be used in the calibration process of your CELL-DYN 1700 System. The same blood samples run on the calibrated hematology instrument will be run on the CELL-DYN 1700 System to be calibrated.

Preparing Pre-Diluted Solution Using the [1/250 DILUTION] Method

1. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**. Press **[MORE]** twice.
2. Obtain the sample of calibrator or all five samples of fresh whole blood (depending on which was used for reference values) and mix the samples well before running. If calibrator material is used, follow the mixing instructions on the package insert; if fresh whole blood is used, invert each tube at least ten times before using. Do not shake the specimens.

   NOTE: If calibrator is used, obtain three CELL-DYN Counting Cups. If fresh whole blood is used, obtain fifteen CELL-DYN Counting Cups. Label three cups as #1, three cups as #2, etc.

   NOTE: Use only CELL-DYN Counting Cups. Using other cups may cause spurious results.

3. Place the well-mixed fresh whole blood or calibrator sample under the Open Mode Sample Probe and press **[1/250 DILUTION]**. If fresh whole blood, start with sample #1. After the sample has been aspirated, remove the sample tube.
4. Hold a clean CELL-DYN Counting Cup under the Open Mode Sample Probe. Hold the cup at a slight angle so that the fluid dispensed from the probe flows down the side of the cup to the bottom — if the cup is held straight, the force of the dispensing fluid may cause fluid to splash out of the cup.
5. Press **[1/250 DILUTION]**. (This key is now highlighted in dark blue.) A diluted specimen dispenses into the Counting Cup.

6. Remove the cup after the solution has been dispensed. Fold the cup once at the upper crease, grip firmly in the middle of the fold, and invert the cup a minimum of five times to thoroughly mix the blood and diluent. (Refer to the following figure.)

WARNING: Potential Biohazard. Consider all specimens potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

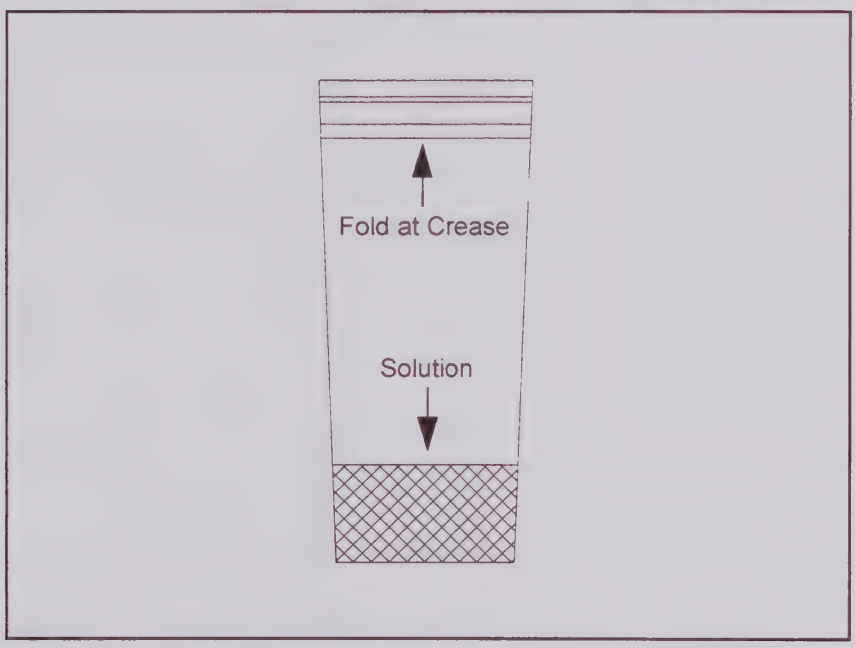

Figure 6.1: CELL-DYN Counting Cup

7. If calibrator material is used, repeat steps 3 through 6 two more times to obtain a total of three cups of diluted specimen.

   If fresh whole blood is used, repeat steps 3 through 6 two more times using sample #1 and the two remaining cups labeled #1. Then repeat steps 3 through 6 three more times for each of the remaining four samples to obtain a total of 15 diluted specimens. Make sure the cup numbers correspond to the proper sample number.

   NOTE: The pre-diluted solutions are stable for 20 minutes. Therefore, the operator must prepare the 15 dilutions as efficiently as possible and run them as soon as possible.

8. When all of the cups of diluted specimens have been prepared, press [MAIN] to return to the MAIN MENU. Proceed with the instructions in ***Pre-Dilute Mode Calibration, Activating the Pre-Dilute Mode*** within this section. Then proceed with the instructions in either ***Auto-Cal Procedure — Calibrator and Fresh Whole Blood*** or ***Enter Factor Procedure — Calibrator and Fresh Whole Blood*** within this section.

Preparing Pre-Diluted Solution Using the [10 mL DISPENSE] Method

1. In the MAIN MENU, press [SPECIAL PROTOCOLS]. Press [MORE] twice.
2. Press [10 mL DISPENSE] to activate the dispense mode. (This key is now highlighted in dark blue.)

   NOTE: If calibrator is used, obtain three CELL-DYN Counting Cups. If fresh whole blood is used, obtain fifteen CELL-DYN Counting Cups and label three cups as #1, three cups as #2, etc.

   NOTE: Use only CELL-DYN Counting Cups. Using other cups may cause spurious results.

3. Hold a clean CELL-DYN Counting Cup under the Open Mode Sample Probe. (If fresh whole blood is used, select one of the cups labeled #1.)Hold the cup at a slight angle so that the fluid dispensed from the probe flows down the side of the cup to the bottom — if the cup is held straight, the force of the dispensing fluid may cause fluid to splash out of the cup.
4. Press [10 mL DISPENSE] to dispense 10 mL (milliliters) of diluent into the cup.
5. If calibrator material is used, repeat steps 3 and 4 two more times to obtain a total of three cups of diluent.

   If fresh whole blood is used, repeat steps 3 and 4 two more times using the two remaining cups labeled #1. Then repeat steps 3 and 4 three more times for each of the remaining four samples to obtain a total of fifteen cups of diluent. It may be advisable to dispense extra 10-mL aliquots of diluent into CELL-DYN Counting Cups in case extra pre-diluted specimens need to be made for any reason.

NOTE: The pre-diluted solutions that will be prepared in the following steps are stable for 20 minutes. It would be difficult to prepare the total of fifteen dilutions (three from each of the five whole blood specimens) within the 20-minute stability period. Therefore, three dilutions will be prepared of each whole blood specimen and the three will be run in the calibration method of choice (either Auto-Cal or Enter Factor), before the next three dilutions are prepared from the next whole blood specimen.

6. Obtain the sample of calibrator or all five samples of fresh whole blood (depending on which was used for reference values), and mix the samples well before using. If using calibrator material, follow the mixing instructions on the package insert. If using fresh whole blood, invert each tube at least ten times before using. Do not shake the specimens.
7. Obtain a 40-µL end-to-end micropipette (available from Abbott). Hold the micropipette near one end, but so that both ends are visible. Insert the tip of the other end into the sample. Tilt the micropipette at an angle that will allow the blood to flow completely to the opposite end.
8. Remove the micropipette from the sample and carefully roll the outside of the micropipette across a lint-free pad slightly dampened with diluent to remove all excess blood. Gently wipe the outside of the micropipette, if necessary. Do not remove any of the sample from inside the micropipette while wiping the outside.

   NOTE: The micropipette is calibrated to contain exactly 40 µL of sample. Check both ends of the micropipette to make sure that it is still completely full of blood after the outside has been wiped.

9. Drop the filled micropipette immediately into one of the CELL-DYN Counting Cups containing 10 mL of diluent, which were prepared in the preceding steps. (If using fresh whole blood, use one of the cups labeled #1.) Fold the cup once at the upper crease (with the micropipette still inside), grip in the middle of the fold, and invert a minimum of 15 to 20 times to thoroughly mix the blood and diluent. (See the following figure.) Mix until the fluid inside the capillary is the same color as the rest of the fluid.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

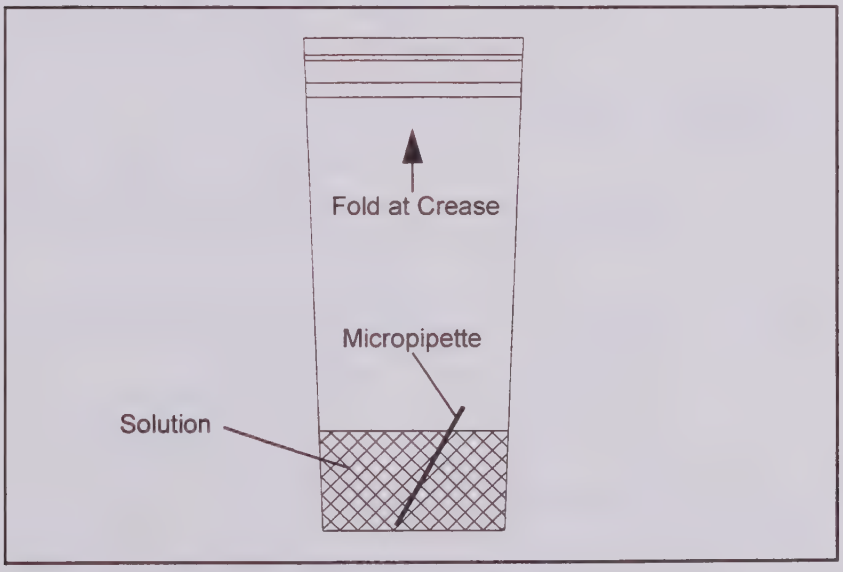

Figure 6.2: CELL-DYN Counting Cup with Micropipette

10. If calibrator material is used, repeat steps 6 through 9 two more times, using the two remaining cups of diluent and two new micropipettes, to obtain a total of three diluted specimens.

    If fresh whole blood is used, repeat steps 6 through 9 two more times using the remaining two cups labeled #1.

11. Proceed with the instructions which follow in ***Activating the Pre-Dilute Mode.*** Then proceed with the instructions in either ***Auto-Cal Procedure — Calibrator and Fresh Whole Blood*** or ***Enter Factor Procedure — Calibrator and Fresh Whole Blood*** within this section.

Return to this step after the three dilutions have been run. Repeat steps 6 through 9 three more times for the next whole blood specimen, using appropriately labeled cups and new micropipettes. Make sure the cup numbers correspond to the proper sample number.

Proceed with either the Auto-Cal or Enter Factor Method of calibration after each set of three dilutions has been made from each sample.

Activating the Pre-Dilute Mode

1. In the main CALIBRATION menu, press [PRE-DILUTE] to activate the Pre-Dilute Mode. The Sample Probe is raised and positioned over the RBC/PLT Mixing Chamber, and PRE-DILUTE MODE is displayed on the screen.

WARNING: Potential Biohazard. Consider all specimens potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

2. Remove the Upper Front Cover. Refer to the instructions for removing the Upper Front Cover in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Flow Panel Inspection and Installation*.**

CAUTION: To prevent damage to the Sample Probe, always confirm that the probe has been raised before attempting to remove the Upper Front Cover.

NOTE: The ground wire must be detached to completely remove the Upper Front Cover.

Auto-Cal Procedure — Fresh Whole Blood and Calibrator

1. In the Pre-Dilute Mode, press [AUTO-CAL SELECT] to display the AUTOCALIBRATION menu. Press [PRINT] to print the current calibration factors.
2. If calibrator material is used, press [CALIBRATOR]. If fresh whole blood is used, press [WHOLE BLOOD].
3. Use the arrow keys to place the cursor on the first parameter to be calibrated. Use the Enter key to toggle between YES and NO to select the parameters for calibration. When YES is displayed next to the parameter, the cursor is positioned in the value field for that parameter.

4. If calibrator material is used, enter the corresponding three-digit reference assay value for each parameter to be calibrated from the sheet enclosed with the calibrator material.

   If fresh whole blood is used, select sample #1 that was run on the reference instrument (see ***Pre-Dilute Mode Calibration, Determining Reference Values — Pre-Dilute, Auto-Cal*** within this section). Using the means derived from the reference instrument, enter the corresponding mean for each parameter to be calibrated. As each value is entered, the field accepts the value and the cursor automatically moves to the next parameter. Use the arrow keys to skip a parameter.

   NOTE: When entering reference values for MCV, the value field on the calibration screen accepts only a two-digit number. Therefore, when entering MCV reference values from the replicate file mean, follow these instructions.

   - A digit to be rounded is not changed if it is followed by a digit less than five.

     Example: 86.4 would be rounded to 86

   - If the digit to be rounded is followed by a digit greater than five or by five followed by other nonzero digits, it is increased by one.

     Example: 86.6 would be rounded to 87
     86.54 would be rounded to 87

   - When the digit to be rounded to is followed by five it is unchanged if it is even, but increased by one if it is odd.

     Example: 86.5 would be rounded to 86
     87.5 would be rounded to 88

   - All values within the same calculation should be carried out to the same decimal place.

   NOTE: When MCV is selected, the message **Reference value for MCV may be supplied by entering values for RBC and HCT. To do so, press # and enter values when prompted** appears in the lower screen. When the pound (#) key is pressed, MCV changes to RBC, allowing the operator to enter the red blood cells reference value (using three digits). Then **<HCT>** appears, allowing the operator to enter the hematocrit reference value. The computer-calculated MCV reference value must be within the normal range of 80 to 100 to be accepted and displayed.

5. If calibrator material is used, select one of the counting cups of the diluted specimen obtained under either the **[1/250 DILUTION]** Method or the **[10 mL DISPENSE]** Method described earlier.

   If fresh whole blood is used, select one of the cups of diluted specimen labeled #1 obtained under either the **[1/250 DILUTION]** Method or the **[10 mL DISPENSE]** Method described earlier.

6. Mix the counting cup again by inverting it several times, and carefully pour the specimen into the Pre-Mixing Cup.

CAUTION: If the **[10 mL DISPENSE]** Method was used, the micropipette is still inside the cup; be careful when pouring to prevent it from falling into the Pre-Mixing Cup.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

CAUTION: If a pre-diluted solution has been inadvertently poured into the Pre-Mixing Cup prior to returning to the **RUN** or **CALIBRATION** menu, it will be necessary to follow the instructions in **Section 5: *Operating Instructions,* Subsection: *Running Samples — Pre-Dilute Mode, Removing a Pre-Diluted Solution from the Pre-Mixing Cup***. Otherwise the flow sequence of the instrument will be incorrect, resulting in overfilling of the WBC Transducer and carryover of the pre-dilution into the next analysis.

7. When READY appears on the screen, press the Touch Plate to activate the Pre-Dilute cycle. The Analyzer performs RUN 1 measurement and displays the values in the RUN 1 column.

   NOTE: The Auto-Cal program automatically compares the results of the first run of the whole blood specimen with the parameter reference values entered for that sample to verify that the difference is in within acceptable limits. If any of the runs fails this Reference Check, the results are highlighted and no calibration factor will be calculated for that parameter. See **Section 6: *Calibration Procedures,* Subsection: *Calibration Troubleshooting***.

8. If calibrator material is used, repeat steps 6 and 7 two more times using the remaining two diluted counting cups to obtain results for RUN 2 and RUN 3. The Factor and Mean Factor for each parameter to be calibrated are calculated by the system after three "good" runs. The calibration factors are saved and the instrument is now calibrated.

   If fresh whole blood is used, repeat steps 6 and 7 two more times using the remaining two diluted Counting Cups labeled #1 to obtain results for RUN 2 and RUN 3. Repeat steps 4 through 7 three more times for each of the remaining four samples. Remember to enter the new values that correspond with each of the remaining four samples before running the specimen. A new factor for each parameter to be calibrated will be calculated each time three runs are completed for a sample. When all five samples have been run in triplicate (15 runs), the instrument is calibrated.

   If after five specimen runs the Factor and Mean Factor have not been calibrated, it may be due to one of the following conditions:

   > < is displayed in the Factor column and a Mean Factor will not be calculated and displayed, if the instrument fails the Precision Check. After three "good" runs, the instrument performs a Precision Check for each parameter being calibrated before determining the Factor and Mean Factor for that parameter. See **Section 6: *Calibration Procedures,* Subsection: *Calibration Troubleshooting.***

   >>> or <<< is displayed in the Factor column and a Mean Factor is not calculated if the instrument fails the Allowable Limits used for calculating the Mean Factor.

9. Press **[RETURN]** to save the Calibration Factors.
10. Press **[PRINT]** to print a copy of the New Calibration Factors.
11. Press **[RETURN]** to return to the **CALIBRATION** menu.
12. Press **[MAIN]** to return to the **MAIN MENU**.
13. Press **[RUN]** to display the **RUN** menu.
14. Run three levels of controls in the Pre-Dilute Mode. Confirm that the results obtained for all parameters are within control limits specified on the assay sheet or within your own established laboratory ranges for the current lot number.

    NOTE: If the results for any parameter are consistently out, repeat calibration or obtain technical assistance by contacting the Abbott Customer Support Center.

Enter Factor Procedure — Calibrator and Fresh Whole Blood

1. Open an empty replicate file.
2. Be sure that READY is displayed in the Status Box on the **RUN** screen, and that the results will go into the empty replicate file chosen in step 1.
3. Remix the pre-diluted specimen in Counting Cup #1 (or the calibrator Counting Cup) by closing the cup and folding once at the upper crease. Invert it a minimum of five times.
4. Carefully pour the dilution into the Pre-Mixing Cup. (For the location of this cup, refer to ***Figure 1.3, Flow Panel — Open Mode View***.)

CAUTION: If the **[10 mL DISPENSE]** Method was used, the micropipette is still inside the cup; be careful when pouring to prevent it from falling into the Pre-Mixing Cup.

WARNING: **Potential Biohazard.** Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

CAUTION: If a pre-diluted solution has been inadvertently poured into the Pre-Mixing Cup prior to returning to the **RUN** or **CALIBRATION** menu, it will be necessary to follow the instructions in **Section 5: *Operating Instructions*, Subsection: *Sample Analysis, Running Samples — Pre-Dilute Mode, Removing a Pre-Diluted Solution from the Pre-Mixing Cup***. Otherwise the flow sequence of the instrument will be incorrect, resulting in overfilling of the WBC Transducer and carryover of the pre-dilution into the next analysis.

5. Press the Touch Plate to start the Pre-Dilute cycle.
6. When the cycle is complete, make sure that there are no **FLOW ERR** or **CLOG** error messages, then repeat steps 3 through 5 with the remaining two pre-diluted solutions of whole blood specimen #1 (or of the calibrator).

7. Prepare three pre-diluted solutions for whole blood specimen #2 and repeat steps 3 through 5, making sure that the instrument is in the Pre-Dilute **RUN** menu before pouring each of the diluted solutions into the Pre-Mixing Cup.
8. Repeat step 7 with the remaining three whole blood specimens for a total of 15 valid runs (no **FLOW ERR** or **CLOG** messages).
9. Press **[MAIN]**. Press **[QUALITY CONTROL]**, followed by **[REPLICATES]**, and select the replicate file which was just used to store the calibration results.
10. Press **[VIEW QC LOG]** and press **[PRINT QC LOG]** to print the summary report for the selected replicate file. Return to **MAIN MENU**.
11. Press **[CALIBRATION]** to display the Whole Blood Pre-Dilute Mode Sample Factors screen. Press **[PRINT]** to obtain a copy of the Current Pre-Dilute Mode Calibration Factors which will be used in determining the new calibration factors.
12. To determine the new calibration factor:

    Use the reference mean values determined in ***Pre-Dilute Mode Calibration, Determining Reference Values — Pre-Dilute, Enter Factor Calibration Procedure*** within this section and the CELL-DYN Mean values determined in steps 4 through 10. Enter this information in the Enter Factor Pre-Dilute Sample Mode Whole Blood Calibration Worksheet provided at the end of this section to calculate the New Pre-Dilute Sample Calibration Factor for each parameter as follows:

    Calibrator Calibration:

    $$\frac{\text{Calibrator Mean}}{\text{CELL-DYN Mean}} \times \text{Current Pre-Dilute Mode Calibration Factor} = \text{New Pre-Dilute Sample Calibration Factor}$$

    Whole Blood Calibration:

    $$\frac{\text{Reference Mean}}{\text{CELL-DYN Mean}} \times \text{Current Pre-Dilute Mode Calibration Factor} = \text{New Pre-Dilute Sample Calibration Factor}$$

    For example, if the reference mean for WBC is 6.6, the Pre-Dilute CELL-DYN Mean for WBC is 7.1, and the Current Pre-Dilute Mode Factor for WBC is 0.98, then:

    $$(6.6 / 7.1) \times 0.98 = 0.91$$

13. With the Pre-Dilute **CALIBRATION** menu displayed, press **[ENTER FACTOR]**.

14. Use the arrow keys to select the first factor to be changed. Enter the three-digit New Calibration Factor calculated from step 12. The cursor automatically advances to the next factor. Use the arrow keys to select a parameter.

    NOTE: **[RESTORE FACTORS]** is used to recall factors, stored on the Hard Disk, corresponding to the current mode – Open, Closed, or Pre-Dilute. **[RESET ALL TO 1.00]** is used to reset all factors displayed on the screen to 1.00.

15. Press **[RETURN]** to save the calibration factors.

16. Press **[PRINT]** to print a copy of the Pre-Dilute Calibration Factors.

17. Press **[MAIN]** to return to the **MAIN MENU**.

18. Confirm calibration of the CELL-DYN 1700 System by the following method:

    Run three levels of controls using the Pre-Dilute Mode. Confirm that the results obtained for all parameters are within the control limits specified on the assay sheet or within your own established laboratory ranges for the current lot number.

    NOTE: If the results for any parameter are consistently out, repeat calibration or obtain technical assistance by contacting the Abbott Customer Support Center.

MPV Latex Calibration Method

This procedure is performed by an authorized Abbott representative.

Calibration is required when mean platelet volume (MPV) values for QC (Quality Control) specimens indicate that MPV is out of calibration.

NOTES

Calibration Troubleshooting

Results from a run can be rejected due to a system fault or because the results were outside a predetermined range. The causes are listed below.

1. Fault Indicators

   If a fault occurs, one of the following Fault Indicators will appear in the **RUN** column for that specimen:

   "K" indicates a Clog
   "FE" indicates a Flow Error

   If one of these Fault Indicators appears, the results for that specimen will be excluded from the Factor and Mean Factor calculations. It may be necessary to repeat this run.

2. Flags (for PLT Only)

   An interference may cause one of the following flags to appear in the Run column for that specimen.

   URI
   LRI
   MRI (Multiple Region Interference: appears only if the specimen generates both a URI and LRI)

   For an explanation of the URI and LRI flags, refer to **Section 3: *Principles of Operation,* Subsection: *Operational Messages and Data Flagging, Parameter Flagging Messages.*** If a flag appears, the results will be excluded from the Factor and Mean Factor calculations. It may be necessary to obtain a replacement sample.

3. Reference Check

   For each parameter being calibrated, the instrument performs a Reference Check on the result from each run. If a result fails the Reference Check, that result is highlighted on the screen, indicating it will be excluded from the Factor and Mean Factor calculation. It may be necessary to obtain a replacement sample. (See limits in ***Auto-Cal Method, Sample Requirements for Calibrator and Fresh Whole Blood*** within this section.) If a parameter result is highlighted, follow the ***Procedure for Corrective Action*** within this section.

4. If the result for a specific parameter exceeds the upper limit of the Reportable Range, chevrons will be displayed instead of a value, and the result will be excluded from the Factor and Mean Factor calculation. It may be necessary to obtain a replacement sample.

5. Precision Check

   After three "good" runs, the instrument will perform a Precision Check for each parameter being calibrated before determining the Factor and Mean Factor for that parameter. If a parameter fails the Precision Check, the highlighted indicator > < will be displayed in the Factor column instead of a value, and no Factor or Mean Factor will be calculated for that parameter. (The Precision Check ensures that the difference between the maximum value and the minimum value does not exceed acceptable limits.)

   If a Precision Check indicator is received, re-input the three-digit target calibration value (derived from the calibrator assay sheet or from a reference instrument) for that parameter and run the specimen again.

6. Allowable Values Exceeded

   - Auto-Cal >>> or <<< — If the resultant Auto-Cal factors exceed allowable values, then >>> (over range) or <<< (under range) is displayed. Verify the results and, if the problem persists, contact the Abbott Customer Support Center.

   - Enter Factor — If a calibration factor entry is attempted exceeding the allowable range, the instrument will not accept the entry.

Procedure for Corrective Action

After three runs, if a Factor and Mean Factor have not been calculated for each parameter to be calibrated, the operator has the following choice:

1. Continue running specimens. The program allows the operator to run a maximum of five specimens to determine Factor and Mean Factor.
2. Press **[ABANDON]** to stop the calibration process for this specimen without deleting the Factor and Mean Factor for specimens already run. Depending on the calibration method being used, the **CALIBRATOR CALIBRATION** menu, the **WHOLE-BLOOD CALIBRATION** menu, or the **MPV LATEX CALIBRATION** menu will be displayed.

   ⚠ **CAUTION:** Do not press **[RESET FACTORS]** between specimen runs. This key is used to delete the Mean Factor for all specimens run prior to pressing the key.

3. If after five runs the program still does not have acceptable results from three runs for each parameter to be calibrated, the operator should do the following:
   - Press **[RETURN]** to return to the main **CALIBRATION MENU**. Parameters which have not been calibrated will have the previous calibration method in the Method column and the previous calibration setting in the Factor column. Press the appropriate soft key to return to the **CALIBRATOR CALIBRATION** menu, or the **WHOLE BLOOD CALIBRATION** menu. Use the arrow keys to place the cursor on the parameter(s) to be calibrated and press Enter to select the parameter. Enter a value for that parameter and rerun the specimens.
   - If after five runs the parameter(s) has not been calibrated, obtain technical assistance by contacting the Abbott Customer Support Center.

NOTES

Worksheets

Enter Factor Open Sample Mode
Whole Blood Calibration Worksheet

Date: _____

Name: _____

Calculate all calibration factors to two decimal places.

New Open Sample Calibration Factors

$$\frac{\textit{Reference Mean}}{\textit{CD1700 Mean}} \times \textit{Current Open Sample Calibration Factor} = \textit{New Open Sample Calibration Factor}$$

	Reference Mean	÷	CD1700 Mean	×	Calibration Factor	=	New Calibration Factor	Range*
WBC		÷		×		=		0.70 - 1.30
RBC		÷		×		=		0.80 - 1.20
HGB		÷		×		=		0.70 - 1.30
MCV		÷		×		=		0.70 - 1.30
PLT		÷		×		=		0.70 - 1.30

* If factor exceeds limits, **do not calibrate**. Check all calculations and call the Abbott Customer Support Center for assistance.

NOTES

Enter Factor Pre-Dilute Sample Mode Whole Blood Calibration Worksheet

Date: _____

Name: _____

Calculate all calibration factors to two decimal places.

New Pre-Dilute Sample Calibration Factors

$$\frac{\textit{Open Mode Mean}}{\textit{Pre-Dilute Sample Mean}} \times \textit{Current Pre-Dilute Sample Calibration Factor} = \textit{New Pre-Dilute Sample Calibration Factor}$$

	Open Mode Mean	÷	Pre-Dilute Sample Mean	×	Pre-Dilute Sample Calibration Factor	=	New Pre-Dilute Sample Calibration Factor	Range*
WBC		÷		×		=		0.700 - 1.300
RBC		÷		×		=		0.800 - 1.200
HGB		÷		×		=		0.700 - 1.300
MCV		÷		×		=		0.700 - 1.300
PLT		÷		×		=		0.700 - 1.300

* If factor exceeds limits, **do not calibrate**. Check all calculations and call the Abbott Customer Support Center for assistance.

NOTES

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CELL-DYN® 1700 SYSTEM

Operational Precautions and Limitations

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Operational Precautions and Limitations

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NOTES

Overview

This section deals with the precautions that need to be taken to ensure the performance and validity of the CELL-DYN® 1700 System and its test results.

The following icons and labels are used to warn the operator of potential dangers or hazards:

WARNING: **Potential Biohazard.** The *biohazard* icon alerts users to an activity or area where they may be exposed to infectious materials or substances.

WARNING: **Electrical Shock Hazard.** The electrical warning icon alerts users to the possibility of electrical shock in the described activity or at the posted location.

The following system precautions and limitations are reviewed in this section:

- General Limitations
- Location Requirements
- Electrical Safety Requirements
- Mechanical Safety Precautions
- Reagent Storage and Handling
- Printer Precautions

For information on substances and conditions that may interfere with system function, see ***Appendix B, Table B-1***.

Limitations

The CELL-DYN 1700 System is designed for *in vitro* diagnostic use.

- Abbott has designed the CELL-DYN 1700 System components for optimal performance. Substituting reagents, calibrators, controls, and components manufactured by other companies may adversely affect the performance of the instrument.
- Follow the recommended maintenance schedules and procedures as outlined in **Section 9: *Service and Maintenance***.
- During the warranty period, all service and repair must be performed by Abbott-authorized representatives.

Location Requirements

The location of the CELL-DYN 1700 System is an important consideration that affects proper instrument functioning, operating safety, and ease of use.

- An Abbott-authorized representative must install the instrument.
- The location should have nonporous, nonabsorbing work surfaces and flooring that can be cleaned easily and disinfected using recommended procedures.
- Place the CELL-DYN 1700 System on a hard, level surface. Locate the system:
  - away from direct sunlight.
  - away from the path of a cooled air or heated air outlet.
  - away from other instruments that may interfere with the CELL-DYN 1700 System, such as drying ovens, centrifuges, x-ray equipment, CRTs or computers, video terminals, copiers, ultrasonic cleaners, and patient areas.
- Do not place reagent containers above the Analyzer.
- The following space should be available to ensure proper ventilation:
  - Bench top space: approximately 4 linear feet plus sufficient space for reagents
  - Behind the instrument: 6 inches of space for proper ventilation
  - Left side of instrument: 6 inches of space for proper ventilation
  - Adequate space around the instrument to perform necessary maintenance procedures
- Care should be taken to prevent blocking of the air vents or fans on the sides and the back of the instrument.
- Before operating the instrument for the first time, verify that each reagent line is connected to the appropriate inlet and reagent container. Refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Tubing and Diluent Syringe Installation.***

- Make sure the waste line is connected to the appropriate outlet and routed to a suitable waste container or drain. If the waste is routed to a waste container, make sure the waste sensor is properly connected. If the waste is routed to a drain, make sure a Dummy Plug is inserted in the Waste Sensor Connector.

Electrical Safety Precautions

To ensure safe operation of the CELL-DYN 1700 System:

- Do not disconnect any electrical connection while the power is ON.
- Use only the approved power cords supplied with the unit. Connect power cords only to properly grounded outlets.

WARNING: Electrical Shock Hazard. Disconnect the machine from electrical power by unplugging the Power Cord before removing any instrument panel that is securely fastened in place by screws or prior to replacing any internally or externally accessible fuses. Replace and secure all instrument panels and electrical grounds prior to restoring power.

- Replace only the externally accessible, labeled fuse located immediately above the Power Cord Connector on the Rear Panel of the instrument. Use a replacement fuse of the specified type and electrical rating only. For detailed instructions, refer to **Section 9: *Service and Maintenance.***

Mechanical Safety Precautions

To ensure safe operation of the CELL-DYN 1700 System:

- Wear gloves and safety glasses and use caution when performing any maintenance procedure on the following components, as they can pinch or puncture:
  - Open Mode Sample Probe
  - Closed Sample Needle (CS model)

WARNING: Potential Biohazard. The needle tips (CS model) are sharp and potentially contaminated with infectious materials. Avoid any contact with the needle tips.

Reagent Storage and Handling

- Store reagents, calibrators, and controls according to the directions contained in the package inserts.
- Protect reagents from extreme heat and freezing during storage. Temperatures below 0°C (32°F) may cause layering that changes the tonicity and conductivity of the reagent. If freezing occurs, do not use the reagent.
- Protect reagents from direct sunlight, evaporation, and contamination. Use the Reagent Container Cap attached to each length of inlet tubing to minimize evaporation and contamination.
- Never add remaining reagent from a container being replaced to a freshly opened container. This may contaminate the new reagent.
- Never use a hemoglobin standard designed for use with Reference Cyanmethemoglobin Methodology directly on the CELL-DYN 1700 System. The CELL-DYN 1700 System uses a Modified Hemiglobincyanide Method which is not designed to analyze these standards directly.

Printer Precautions

The Printhead can get very hot during extended periods of printing. Allow it to cool before touching it.

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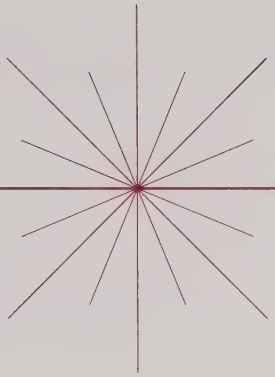
CELL-DYN® 1700 SYSTEM



Hazards

Hazards

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NOTES

Overview

The CELL-DYN® 1700 System contributes to laboratory safety by reducing personnel exposure to biohazards. This does not reduce the importance of biosafety awareness where such hazards exist, however, and it adds the need for awareness of risks inherent in electromechanical equipment operation.

This section provides information about personal injury hazards that might be encountered while operating this system. The focus of this section is on biohazards. For information on electrical and mechanical precautions, refer to **Section 7: *Operational Precautions and Limitations.*** Discussions of actions or conditions that could adversely affect the system or its performance appear in relevant sections throughout this manual.

General Biosafety Warning

WARNING: **Potential Biohazard.** Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, safe laboratory working procedures when handling these samples. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Safety Requirements for Handling Sample Aspiration Probes

WARNING: **Potential Biohazard.** The probe is sharp and potentially contaminated with infectious materials (e.g., patient samples, reagents, and controls). Avoid any unnecessary contact with the probe.

Infection Control

To safeguard against the transmission of infectious agents, observe the following precautions:

- Do not smoke, eat, or drink in areas where test samples are handled.
- Never pipette by mouth.

Chemical Hazards

Exposure to potential hazards of chemicals used in the operation and maintenance of the CELL-DYN® 1700 System should be prevented by the use of information on Material Safety Data Sheets (MSDS) and proper personal protective equipment, work procedures, and equipment as specified on the OSHA Hazard Communication Standard (29 CFR Part 1910.1200).

Safety Icons

Safety icons in the text of this manual are used to identify potentially dangerous conditions or situations. A brief explanatory message labeled **WARNING** or **CAUTION**, depending on the nature of the hazard, accompanies the icon.

For a summary of locations in the manual where safety icons are referenced, refer to the **Master Table of Contents**, ***List of Safety Icons***.

WARNING: Potential Biohazard. The biohazard icon alerts users to an activity or area where they may be exposed to infectious materials or substances.

WARNING: Electrical Shock Hazard. The electrical warning icon alerts users to the possibility of electrical shock in the described activity or at the posted location.

WARNING: The general warning icon alerts users to a potential health or safety hazard.

CAUTION: The general caution icon appears adjacent to an explanation of conditions that could interfere with the proper functioning of the instrument.

Decontamination Procedures

The OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) requires the decontamination of laboratory equipment prior to servicing or shipment:

- Decontaminate the instrument by performing the Auto-Clean cycle. This cycle flushes all of the fluid pathways with reagents to purge any waste from the fluid pathways. (The Open Mode Sample Probe and the CS Needle are automatically rinsed after every cycle.) The surfaces of the instrument should be wiped with a nonabrasive detergent solution to remove any soiling, then wiped with a tuberculocidal disinfectant, such as a 10% solution of filtered bleach.
- If the instrument is to be shipped, it must be decontaminated prior to shipment. This is accomplished by pressing the [CLEAN FOR SHIPPING] key in the SPECIAL PROTOCOLS menu. Instructions for this procedure are given in **Section 9:** ***Service and Maintenance,*** **Subsection:** ***Nonscheduled Maintenance Procedures, Preparing the Analyzer for an Extended Period of Non-Use or for Shipping.***

Blood Samples

- Decontaminate and dispose of all specimens and potentially contaminated materials in accordance with local, state, and federal regulations.
- Waste liquid is a possible source of biological and chemical hazard. Handle with extreme care during the disposal process. Adding disinfectants to the waste container helps to inactivate infectious organisms that may collect with the waste. This reduces the risk of infecting personnel who handle this material. Filtered bleach and glutaraldehyde solutions effectively inactivate organisms such as HBV, HCV, and HIV and can be used for this purpose. Appropriate protective clothing must be worn when handling these substances.
- For precautions and limitations pertaining to sample collection and handling, refer to **Section 5:** ***Operating Instructions,*** **Subsection:** ***Specimen Collection and Handling.***

Spills

- Clean up spills of potentially infectious materials in accordance with established biosafety practices. A generally accepted procedure for the cleanup of such spills is to absorb the spill with toweling or other absorbent material, wipe the area with a detergent solution, and then wipe the area with an appropriate tuberculocidal disinfectant, such as a 10% solution of filtered bleach.

Handling Waste and Waste Containers

Waste

Dispose of all clinical specimens, reagents, controls, calibrators, standards, cuvettes, and other disposables that may be contaminated, in accordance with local, state, and federal regulations governing the treatment of regulated medical waste.

Sharps

Sharps, such as contaminated probes, must be placed in an appropriately marked, puncture-resistant container prior to treatment and disposal.

Solid Wastes

Generally accepted procedures for the treatment of potentially infectious solid wastes include incineration or autoclaving. If an autoclave is used, you should verify the effectiveness of the decontamination cycle.

Liquid Wastes

Liquid wastes containing acid should be neutralized prior to the addition of a disinfectant and disposal.

NOTES

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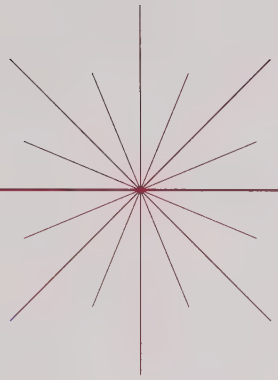
CELL-DYN® 1700 SYSTEM



Service and Maintenance

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Service and Maintenance

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NOTES

Overview

The CELL-DYN® 1700 System is designed to require minimal routine maintenance. For example:

- The fluidics are automatically rinsed between samples.
- The instrument is automatically placed in STANDBY if it has been idle for four hours (or other operator-definable duration) after the last cycle is completed.

The operator is encouraged to routinely perform the required maintenance to lengthen the operational life of the instrument and to minimize system problems that lead to imprecision and inaccuracy. This section describes the recommended preventive maintenance procedures and provides instructions for preparing the instrument for an extended period of inactivity.

> **NOTE:** After performing any maintenance procedure, run background counts until acceptable results are obtained for all background parameters (WBC, RBC, HGB, and PLT).

Many required preventive maintenance procedures have been automated on the CELL-DYN 1700 System. These programs are accessed by pressing **[SPECIAL PROTOCOLS]** on the **MAIN MENU**. The **SPECIAL PROTOCOLS** menu is discussed in the next subsection.

WARNING: Potential Biohazard. Consider all specimens, reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling these samples. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

CAUTION: Powder from the use of some gloves may cause instrument problems. Wear powder-free gloves when performing maintenance procedures. The gloves must, however, be capable of preventing exposure to chemical and biohazards.

Following outlined maintenance schedules will minimize operational problems with the CELL-DYN 1700 System. The recommended intervals are based on the instrument operating in laboratories that process samples from a general patient population. The intervals are affected by the number of samples processed, the workload schedule, the operating environment, and the patient population that is analyzed. Each laboratory must assess its own situation and modify these recommended intervals as necessary. Overdue maintenance is usually indicated by imprecision of one or more of the directly measured parameters. This imprecision is due to carryover or dilution/sampling inconsistencies. If this occurs on more than a random basis, perform the appropriate maintenance more frequently than indicated.

If you encounter trouble performing any of these procedures, contact the Abbott Customer Support Center at 1 (800) CELL DYN.

To order any parts, accessories, or consumables, refer to ***Appendix A — Parts and Accessories.***

For decontamination procedures, refer to **Section 8:** ***Hazards,*** **Subsection:** ***Decontamination Procedures***

Special Protocols Menu

The SPECIAL PROTOCOLS menu is the primary menu used during maintenance procedures. The three main functions of the SPECIAL PROTOCOLS menu are:

- Actuating special functions for routine maintenance
- Priming reagents when any reagent is empty
- Actuating the Auto Shutdown cycle before the instrument is turned OFF

In the MAIN MENU, press [SPECIAL PROTOCOLS] to access the SPECIAL PROTOCOLS menu. There are three levels in the SPECIAL PROTOCOLS menu. At the first two levels, the [MORE] key allows the operator to access a submenu. At the third level, the [MORE] key returns the operator to the main SPECIAL PROTOCOLS menu. A brief description of each soft key, displayed at the bottom of the SPECIAL PROTOCOLS menu, and its function is given below.

Daily Shutdown

[DAILY SHUTDOWN] is used to prepare the instrument for short periods of inactivity (72 hours or less) with power remaining ON, for a prolonged period of inactivity (up to 2 weeks) with power turned OFF, and for some maintenance operations. When the Daily Shutdown cycle is complete, the instrument is placed in STANDBY.

Clean Sampler

[CLEAN SAMPLER] is used to drain and refill the Closed Sample Assembly after manual cleaning. This key is used only on the CELL-DYN 1700CS System; it is blank on the CELL-DYN 1700 System. (Refer to **Section 13: *CELL-DYN 1700CS — Closed Sample Aspiration.***)

Lyse Prime

[LYSE PRIME] is used to prime the instrument with lyse.

Reagent Prime

[REAGENT PRIME] is used to prime the instrument with diluent and detergent.

Auto Clean

[AUTO CLEAN] is used to flush and clean the entire fluidics system with enzyme solution.

More

[MORE] is used to display a new submenu with additional functions.

First Level Subfunction Keys When [MORE] is Pressed

Clean Sample Syringe

[CLN SAMPL SYRINGE] is used to prepare the Sample Syringe for removal and cleaning. When sequentially pressed, this key changes to [SYRINGE DOWN], [RESTORE SYRINGE], then back to [CLN SAMPL SYRINGE].

Clean Dil Syringe

[CLEAN DIL SYRINGE] is used to move the Diluent Syringe up, allowing the operator to remove the Syringe Drive Nut. When sequentially pressed, this key changes to [SYRINGE DOWN], [SYRINGE UP], [RESTORE SYRINGE], then back to [CLEAN DIL SYRINGE].

Clean Lyse Syringe

[CLN LYSE SYRINGE] is used to prepare the Lyse Syringe for removal and cleaning. When sequentially pressed, this key changes to [SYRINGE DOWN], [SYRINGE UP], [RESTORE SYRINGE], then back to [CLN LYSE SYRINGE].

Probe Home/Probe Down

[PROBE HOME] is used to move the Sample Aspiration Probe up and position it over the von Behrens RBC/PLT Transducer (the "home" position). When sequentially pressed, this key changes to [PROBE DOWN] then back to [PROBE HOME].

Drain Baths/Refill Baths

[DRAIN BATHS] is used to drain the transducers prior to cleaning. When sequentially pressed, this key changes to [REFILL BATHS] to refill the transducers when cleaning is finished then back to [DRAIN BATHS].

Second Level Subfunction Keys When [MORE] is Pressed Twice

1/50 Dilution

[1/50 DILUTION] is used to make a 1 to 50 sample dilution (uses 100 µL of sample and 5 mL of diluent). This function is for Abbott Service Representatives only.

1/250 Dilution

[1/250 DILUTION] is used to make a 1 to 250 sample dilution when preparing pre-diluted samples (uses 40 µL of sample and 10 mL of diluent).

Clean for Shipping

[CLEAN FOR SHIPPING] is used to clean the instrument's components — such as transducers, tubing, waste system — prior to shipment or an extended period of inactivity (two or more weeks).

10 mL Dispense

[10 mL DISPENSE] is used to dispense 10 mL of diluent when preparing pre-diluted samples.

NOTES

Preventive Maintenance Schedule

Perform the following procedures at the scheduled time intervals.

Daily

1. Daily Start-Up
2. Daily Shutdown
3. Closed Sample Tube Holder Well cleaning (for the CS model only — refer to **Section 13:** ***CELL-DYN 1700CS — Closed Sample Aspiration,*** **Subsection:** ***Service and Maintenance, Tube Holder Well Cleaning***)

Weekly

1. Open Sample Auto-Clean
2. Aspiration Probe Exterior Cleaning
3. Closed Sample Auto-Clean (for the CS model only — refer to **Section 13:** ***CELL-DYN 1700CS — Closed Sample Aspiration,*** **Subsection:** ***Service and Maintenance, Closed Sample Auto-Clean***)

Monthly

1. Lyse Inlet Tubing Rinse
2. Rear Fan Filter Cleaning

Semiannually

1. Printer Cleaning

As Required (for Troubleshooting or Corrective Action)

For maintenance frequency, refer to ***Nonscheduled Maintenance Frequency*** within this section.

1. Aperture Plates Cleaning
2. Diluent Syringe Cleaning
3. Diluent Syringe Replacement
4. Sample Syringe Cleaning/Replacement
5. Lyse Syringe Cleaning/Replacement
6. Sample Aspiration Probe Interior Cleaning
7. HGB Flow Cell Manual Cleaning
8. Vent Line Cleaning

9. Vacuum Accumulator Draining and Cleaning
10. Aspiration Probe Removal and Replacement
11. Preparing the Analyzer for an Extended Period of Non-Use or for Shipping
12. Fuse Replacement
13. Peristaltic Pump Tubing Removal/Replacement (for the CS model only — refer to **Section 13:** ***CELL-DYN 1700CS — Closed Sample Aspiration,*** **Subsection:** ***Service and Maintenance, Peristaltic Pump Tubing Removal/ Replacement***)

Daily Maintenance Procedures

Daily Start-Up Procedure

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses

Procedure

The daily start-up routine consists of the following procedures:

1. Check the reagent levels and replace reagent containers as necessary.
2. Check printer paper.
3. Check tubing in the Normally Closed Valves for crimps.
4. Run a background count.
5. Run controls according to your laboratory operating procedure.

Daily Shutdown Procedure

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Procedure

If the shutdown time is expected to be 72 hours or less, follow the procedure below.

1. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.

2. Press [DAILY SHUTDOWN] to begin this cycle. PROCESS ACTIVE appears on the screen. The Daily Shutdown cycle takes approximately three minutes.
3. Empty or replace waste container as needed.
4. Record this maintenance in your maintenance log.

NOTE: When the cycle is complete, the instrument should be left with the power ON.

Prolonged Shutdown

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses

WARNING: **Potential Biohazard**. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

If the shutdown time is expected to exceed 72 hours, then power should be turned OFF. If the shutdown time is expected to exceed two weeks, refer to ***Nonscheduled Maintenance Procedures, Preparing the Analyzer for an Extended Period of Non-Use or Shipping*** within this section.

NOTE: For the CS Model, also refer to the Prolonged Shutdown Procedure in **Section 13:** ***CELL-DYN 1700CS — Closed Sample Aspiration,*** **Subsection:** ***Service and Maintenance, Prolonged Shutdown.***

Before turning the power OFF, perform the ***Lyse Inlet Tubing Rinse*** procedure described in ***Monthly Maintenance Procedures*** later in this section, and perform the ***Daily Shutdown Procedure*** described above. Then turn the power OFF and perform the following procedure:

1. Immediately after the power is turned OFF, remove the following tubing:
   - Tubing in the Normally Closed (black octagon) Valve at the top left of the Flow Panel under the Upper Front Cover of the instrument. (Refer to Figure 1.3, Flow Panel — Open Mode View.)
   - Tubing in the three Normally Closed (black octagon) Valves on the lower Left Side of the instrument. (Refer to Figure 1.4, Lower Left Side Panel.)

   ⚠ **CAUTION:** Do not forget to reinsert the tubing securely in the Normally Closed Valves before turning the instrument back ON. Refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Tubing and Diluent Syringe Installation.***
2. Record this maintenance in your maintenance log.

NOTES

Weekly Maintenance Procedures

Open Sample Auto-Clean

Materials Required

1. Gloves.
2. Lab coat.
3. Safety glasses.
4. CELL-DYN Enzymatic Cleaner. (Enzymatic cleaner should be used at room temperature but stored at a temperature between 2°C and 8°C, or between 36°F and 46°F.)

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

1. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
2. Press **[AUTO CLEAN]** to begin this cycle.
3. Place the vial of undiluted enzymatic cleaner concentrate under the Sample Probe.
4. Press **[START CLEAN]**. The solution is aspirated and the message **PROCESS ACTIVE** is displayed on the screen. The complete cycle takes approximately seven minutes.
5. When the cycle is complete, press **[MAIN]** to return to the **MAIN MENU**.
6. Press **[RUN]** followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**.
7. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters (WBC, RBC, HGB, and PLT).
8. Record this maintenance in your maintenance log.

Aspiration Probe Exterior Cleaning

Materials Required

1. Gloves.
2. Lab coat.
3. Safety glasses.
4. CELL-DYN Enzymatic Cleaner. (Enzymatic cleaner should be used at room temperature but stored at a temperature between 2°C and 8°C, or between 36°F and 46°F.)
5. DYN-A-WIPE™ lint-free pads (or other lint-free pads).
6. Deionized water.

WARNING: Potential Biohazard. The probe is sharp and potentially contaminated with infectious materials. Avoid any contact with the probe. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Procedure

During each run cycle, the Wash Block rinses whole blood from the outside of the Aspiration Probe. However, the exterior portion of the probe should be routinely cleaned to ensure it moves freely through the Wash Block. This procedure can be done at any time (at least weekly) or in conjunction with other routine cleaning procedures.

1. With the power ON and Aspiration Probe down, carefully wipe the outside of the probe several times with a DYN-A-WIPE™ lint-free pad (or other lint-free pad) that has been dampened with diluted enzymatic cleaner (one part distilled water to one part enzymatic cleaner).

CAUTION: Moving the probe while wiping it may require reinitialization.

2. Wipe the outside of the probe with a DYN-A-WIPE™ (or other lint-free pad) that has been dampened with distilled water.
3. In the **MAIN MENU**, press **[RUN]** followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**.

4. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
5. Record this maintenance in your maintenance log.

NOTES

Monthly Maintenance Procedures

Lyse Inlet Tubing Rinse

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Medium-sized beaker
5. Warm deionized water

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

1. Fill the beaker with warm deionized water.
2. Remove the Lyse Tubing from the Lyse Reagent Container and place the end of the tubing in the beaker. (The Lyse Tubing should still be attached to the Reagent Inlet Panel).
3. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
4. Press **[LYSE PRIME]** to begin the Lyse Priming cycle.

   NOTE: Disregard any **Lyse Empty** alarm and proceed with next step.

5. Press **[CLEAR ALARM]** several times to perform multiple rinsing cycles with warm water.
6. Remove the lyse tubing from the beaker of water. Keeping the end of the tubing exposed to the air, press **[CLEAR ALARM]** to cycle air through the tubing.
7. Reinsert the tubing into the Lyse Reagent Container and press **[LYSE PRIME]**. Observe the Lyse Syringe to verify that lyse is flowing into the syringe.
8. Press **[LYSE PRIME]** two or three times to perform multiple cycles.
9. Press **[MAIN]** to return to the **MAIN MENU**.
10. Press **[RUN]** followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**.

11. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
12. Record this maintenance in your maintenance log.

Rear Fan Filter Cleaning

Materials Required

1. DYN-A-WIPE™ lint-free pads (or other lint-free pads)

Procedure

The two Rear Panel Fan Filters are used to clean air passing into the instrument. Clean these filters monthly to maintain a constant and unrestricted air flow. More frequent cleaning is required if the unit is located in a dusty area.

1. Perform the Daily Shutdown procedure to place the instrument in STANDBY. (Refer to ***Daily Maintenance Procedures, Daily Shutdown Procedure*** within this section.)
2. Turn the power switch to OFF and locate the Fan Filters on the Rear Panel. (Refer to Figure 1.5, Rear Panel.)
3. Snap off the plastic frame attached to the mounting bracket, holding the filters.
4. Remove the filters and run a medium-pressure stream of warm water over them.
5. Blot dry the filters with a lint-free pad.
6. Reinsert the cleaned filters into the frame and snap the frame back onto the mounting bracket.
7. Turn the power switch to ON. After the instrument is initialized, press **[PRIME/RUN]** to prime the system and place it in the READY state.
8. Record this maintenance in your maintenance log.

Semiannual Maintenance Procedures

Printer Cleaning

Every six months (or after about 300 hours of operation), use a clean, dry cloth to dust the area around the carriage shaft and platen. Be sure to remove any loose particles of paper. Do not use solvents or strong detergents on the cabinet. Be sure to turn the printer OFF and disconnect the power cord before cleaning.

NOTES

Nonscheduled Maintenance Frequency

The following table lists the frequency for nonscheduled maintenance procedures.

Table 9.1: Nonscheduled Maintenance Frequency

Procedure	Frequency
Aperture Plates Cleaning	When Auto-Clean has not cleared a restriction, or an organic buildup is suspected of causing any of the following: 1. Baseline count times that are out of range 2. Background problems 3. Persistent clogs or flow errors NOTE: If available, use a microscope to verify that the aperture plate is entirely clean.
Diluent Syringe Cleaning	When it is suspected to be the source of imprecision. NOTE: Flaking of the white TEFLON® plunger tip indicates that replacement of syringe is necessary.
Diluent Syringe Replacement	When there is flaking of the white TEFLON® plunger tip.
Sample Syringe Cleaning/ Replacement	This procedure is rarely necessary. Replace the syringe when: 1. It is suspected to be the source of imprecision. 2. Black residue appears on the white TEFLON® tip. 3. Salt builds up on the syringe plunger.
Lyse Syringe Cleaning/ Replacement	When it is suspected to be the source of imprecision. NOTE: Flaking of the white TEFLON® plunger tip indicates that replacement of syringe is necessary.
Sample Aspiration Probe Interior Cleaning	When the Sample Aspiration Probe is suspected to be the source of imprecision.
HGB Flow Cell Manual Cleaning	When Auto-Clean has not cleared away a restriction, or an organic buildup is suspected of causing any of the following: 1. Elevated HGB results 2. HGB imprecision
Vent Line Cleaning	When the vent line is restricted and prevents the formation of a proper meniscus in the metering tube.
Vacuum Accumulator Draining and Cleaning	1. When the alarm indicates that the accumulator is wet 2. When background counts exceed specification
Aspiration Probe Removal and Replacement	1. When there is a bent probe 2. When there is a nonremovable obstruction in probe
Fuse Replacement	1. When the fuse fails 2. When changing the power setting form 110/120 VAC to 220/240 VAC or vice versa

Table 9.1: Nonscheduled Maintenance Frequency

Procedure	Frequency
Preparing the Analyzer for an Extended Period of Non-Use or for Shipping	1. When shipping the instrument 2. When storing the instrument 3. Before an extended period of non-use 4. When the entire plumbing system is suspected as the source of bacterial or fungal contamination
Peristaltic Pump Tubing Replacement (for CS models only — refer to **Section 13: *CELL-DYN 1700CS — Closed Sample Aspiration,* Subsection: *Service and Maintenance***)	Tubing is changed based upon volume and usage at individual laboratories.

Nonscheduled Maintenance Procedures

Aperture Plates Cleaning

Materials Required

1. Gloves.
2. Lab coat.
3. Safety glasses.
4. CELL-DYN Enzymatic Cleaner or filtered bleach. (Enzymatic cleaner should be used at room temperature but stored at a temperature between 2°C and 8°C, or between 36°F and 46°F.)
5. Small beaker (50-mL).
6. Camel hair aperture brush (included in the Accessory Kit).
7. Deionized water.

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

1. Press **[SPECIAL PROTOCOLS]** followed by **[MORE]** then **[PROBE HOME]**.
2. Remove the Upper and Lower Front Covers.
3. Press **[PROBE DOWN]**. Locate the von Behrens RBC/PLT Transducer and the von Behrens WBC Transducer. (Refer to the following figure.)

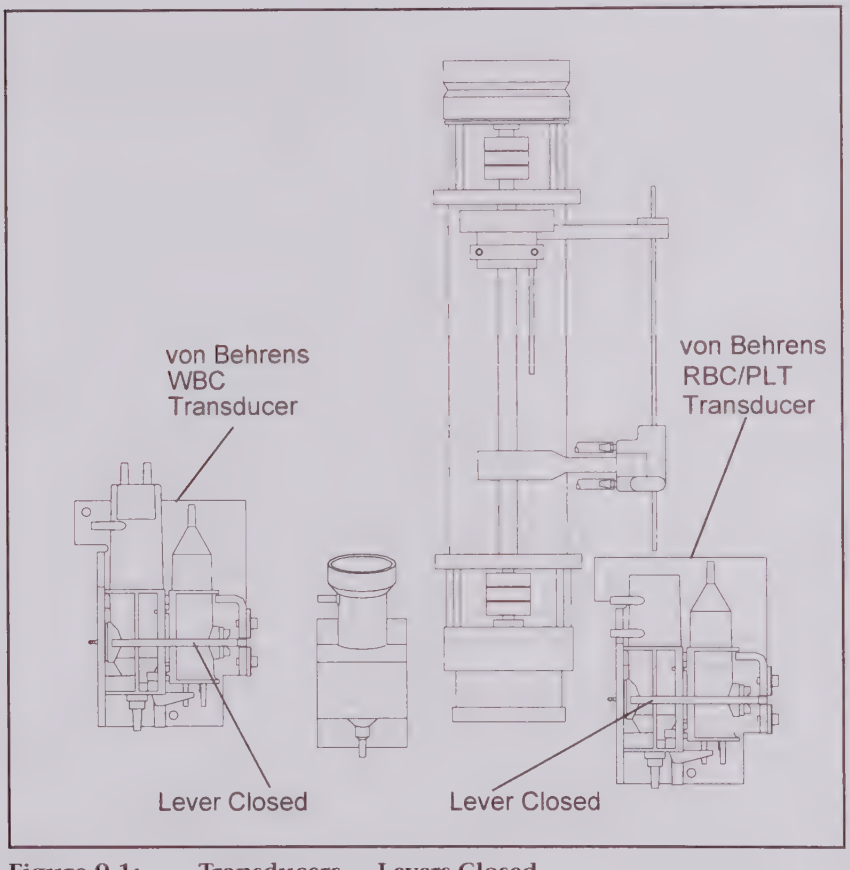


Figure 9.1: Transducers — Levers Closed

4. Press **[DRAIN BATHS]**. Liquid in both chambers of the von Behrens RBC/PLT and WBC Transducers drains to the waste system.

5. Locate the two red tagged levers attached to the von Behrens RBC/PLT and WBC Transducers. These levers hold the aperture plates securely in place. Grasp each lever and swing it all the way to your right. Refer to the following figure.

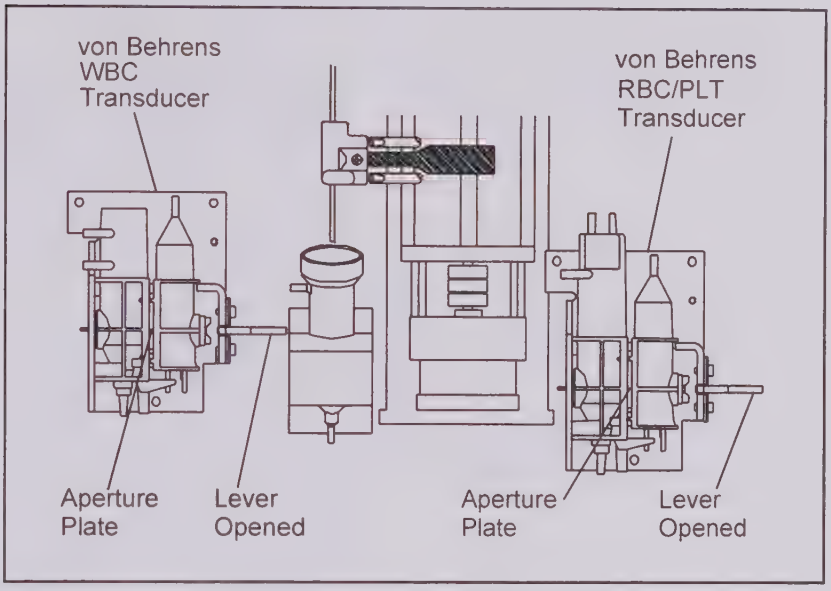


Figure 9.2: Transducers — Levers Opened

6. Grasp the RBC/PLT aperture plate, located in the slot separating the two chambers of the von Behrens RBC/PLT Transducer, and pull it straight out until it is free of the transducer.
7. Grasp the WBC aperture plate, located in the slot separating the two chambers of the von Behrens WBC Transducer, and pull it straight out until it is free of the transducer.
8. Dispense 40 mL of warm deionized water into a beaker or other suitable container and add 40 drops of enzymatic cleaner. (Warm water enhances enzyme action.)

   OR

   Dispense 15 mL of water into a beaker or suitable container and add 5 mL of filtered bleach.

   NOTE: Diluted enzyme cleaner and filtered bleach are most effective when they are prepared fresh each time this procedure is done.

9. Use the camel hair aperture brush provided in the Accessory Kit to clean debris from both sides of each aperture plate. Use a rotating motion to clean the plates.

CAUTION: Use only the brush provided. Using other items or brushes may damage the aperture plate.

10. Place each aperture plate into the beaker of cleaning solution prepared in step 8. Completely immerse each plate in the cleaning solution. Allow the plates to soak for *at least* five minutes and *no longer* than fifteen minutes.
11. Remove each aperture plate from the cleaning solution and thoroughly rinse it with a fine stream of deionized water.

To Reinstall the RBC/PLT Aperture Plate

The RBC/PLT aperture plate is identified with "R/P" etched in the plate and is installed in the von Behrens RBC/PLT Transducer.

1. Position the RBC/PLT aperture plate so the notch is on the lower portion of the edge being inserted into the transducer.
2. Insert the aperture plate into the slot between the two chambers of the von Behrens RBC/PLT Transducer. Push the plate in until it is completely seated in the slot.
3. Swing the red lever all the way to your left to secure the plate in place. (There will be a slight resistance as you move the red lever.)

To Reinstall the WBC Aperture Plate

The WBC aperture plate is identified with "WBC" etched in the plate and is installed in the von Behrens WBC Transducer.

1. Position the WBC aperture plate so the notch is on the lower portion of the edge being inserted into the transducer.
2. Insert the aperture plate into the slot between the two chambers of the von Behrens WBC Transducer. Push the plate in until it is completely seated in the slot.
3. Swing the red lever all the way to your left to secure the plate in place. (There will be a slight resistance as you move the red lever.)

NOTE: Be sure both the RBC/PLT and the WBC aperture plates are installed before pressing the **[REFILL BATHS]** key.

To Fill the Transducers

1. Press [REFILL BATHS]. Both transducers are refilled. Check the right-hand chambers of both transducers to ensure they are completely filled with liquid and that no air bubbles are visible at the top of the chambers.

   NOTE: If air bubbles are observed at the top of the right-hand chamber of either transducer, repeat the process of draining and refilling the baths. If the problem persists, obtain technical assistance.

2. Press [PROBE HOME].
3. Reattach the Lower Front Cover then the Upper Front Cover.
4. Press [PROBE DOWN].
5. Press [MAIN] followed by [RUN], [SPECIMEN TYPE], and [NORMAL BACKGRND].
6. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
7. Record this maintenance in your maintenance log.

Diluent Syringe Cleaning

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Large basin of deionized water at room temperature
5. Deionized water

WARNING: **Potential Biohazard.** Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

1. Obtain a large basin or suitable container to hold and soak the Diluent Syringe. Add 2 to 3 inches of deionized water to the container.
2. Locate the dark plastic door on the left side of the instrument. Using the two finger holes in the plastic door, slide the door up slightly and pull out to expose the syringes. The Diluent Syringe is the large (10-mL) syringe in the center, the Lyse Syringe is the medium (2.5-mL) syringe on the left, and the Sample Syringe is the thin (100-µL) syringe on the right.
3. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
4. Press **[MORE]** followed by **[CLEAN DIL SYRINGE]**. The syringe plunger moves up.
5. Remove the Drive Nut at the bottom of the plunger by holding the Calibration Block with one hand and turning the Drive Nut clockwise (when viewed from above). Refer to the following figure.

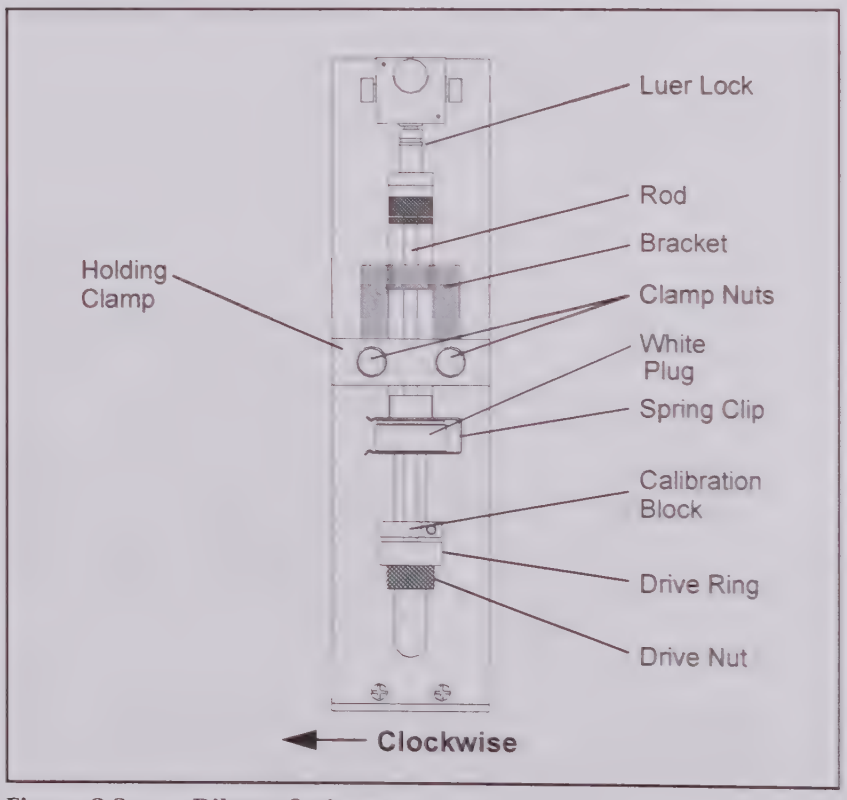


Figure 9.3: Diluent Syringe

6. Press **[SYRINGE DOWN]** to move the Drive Ring down, allowing the syringe to be removed.
7. Completely remove the two Clamp Nuts and front section of the Syringe Holding Clamp.
8. Hold the syringe by the glass barrel and *turn it clockwise* (when viewed from above) to release it from its Luer Lock Fitting. Refer to the preceding figure.

⚠ **CAUTION:** *Do not pull the syringe toward you.* Pull it straight down until it clears the bracket.

9. Remove the Spring Clip from the barrel.
10. Immerse the complete syringe assembly in the container of deionized water prepared in step 1. Allow it to soak for one to two minutes to dissolve accumulated salt deposits.
11. Pull the White Plug out of the barrel of the syringe. Pour deionized water into the barrel from the bottom of the syringe.

⚠ **CAUTION:** Do not pull or push the plunger when it is dry.

12. Remove the plunger from the barrel while the syringe is still immersed in deionized water. Let the barrel and plunger soak in the water for five minutes. Remove and rinse thoroughly with deionized water. Remove excess water by shaking; do not wipe.
13. Reassemble the syringe assembly.
    a. Insert the plunger into the barrel.
    b. Insert the White Plug into the end of the barrel.
    c. Install the Spring Clip on the barrel with the small prongs facing up.

    NOTE: When installing the Spring Clip, wedge the larger opening of the clip over the lip of the barrel and the small opening under the White Plug.

14. Reinstall the syringe into the Luer Lock Fitting by turning it counterclockwise (when viewed from above) until it is finger-tight. *Do not overtighten.*

15. Reinstall the front section of the Syringe Holding Clamp. Secure it with the Clamp Nuts removed earlier. Install the Clamp Nuts with the larger hole facing the screw. Tighten the Clamp Nuts finger-tight with the beveled edge towards the Holding Clamp. *Do not overtighten.*

16. Press [SYRINGE UP] to move the Drive Ring up. Secure the plunger in the plunger holder with the Drive Nut removed earlier. Install the Drive Nut with the spacer (the long narrow end) facing up. Tighten the Drive Nut to finger-tight while holding the Calibration Block. *Do not overtighten.*

    NOTE: A small gap between the plunger holder and the Drive Nut is normal.

17. Press [RESTORE SYRINGE].

    NOTE: Bubbles may be present during the first filling. If they do not disappear, press [MORE] twice, then press [REAGENT PRIME] to clear the bubbles.

18. Press [MAIN] to return to the MAIN MENU.

19. Press [RUN] followed by [SPECIMEN TYPE] and [NORMAL BACKGRND]. Using the Touch Plate, run two to three background counts. Watch the syringe action to make sure it fills and dispenses completely. Run background counts until acceptable results are obtained for all background parameters.

20. Confirm calibration by running controls before running patient samples.

21. Record this maintenance in your maintenance log.

Diluent Syringe Replacement

If the Diluent Syringe needs to be replaced, the Calibration Block must be removed from the old syringe and placed on the new syringe. Follow the procedure above for removing and replacing the syringe. Follow the procedure below for removing and installing the Calibration Block.

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Syringe
5. 7/64" Allen wrench (Accessory Kit)

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Procedure

1. Remove the Diluent Syringe from the instrument as described in steps 2 through 9 of the previous procedure (***Diluent Syringe Cleaning***).
2. Remove the Calibration Block from the old syringe using a 7/64" Allen wrench.
3. If not already off, remove the Spring Clip from the old syringe. Install the Spring Clip on the barrel of the new syringe with the small prongs facing up. (Wedge the larger opening of the clip over the lip of the barrel and the small opening under the white plug.)
4. Install the new syringe in its Luer Lock Fitting by turning it counterclockwise (when viewed from above) until it is finger-tight. *Do not overtighten.*
5. Slide the Calibration Block onto the plunger rod of the new syringe, then press **[SYRINGE UP]** so that the Calibration Block rests on top of the Drive Ring.
6. Reinstall the front section of the Syringe Holding Clamp. Secure it with the Clamp Nuts removed earlier. Tighten the Clamp Nuts finger-tight with the beveled edge toward the holding clamp. *Do not overtighten.*

7. Adjust the position of the plunger so that the white plunger head is slightly below the top of the glass barrel (leaves a gap of 1 division, marked on the syringe barrel, or approximately 200 µL).
8. With the Calibration Block resting on the Drive Ring, tighten the Allen screw so that the Calibration Block is firmly secured to the rod.
9. Install the Drive Nut with the spacer (the long narrow end) facing up. Tighten the large Drive Nut to finger-tight while holding the Calibration Block. *Do not overtighten.*

   NOTE: A small gap between the plunger holder and the Drive Nut is normal.

10. Press [RESTORE SYRINGE].

    NOTE: Bubbles may be present during the first filling. If they do not disappear, press [MORE] twice, then press [REAGENT PRIME] to clear the bubbles.

11. Press [MAIN] to return to the MAIN MENU.
12. Press [RUN] followed by [SPECIMEN TYPE] and [NORMAL BACKGRND]. Using the Touch Plate, run two to three background counts. Watch the syringe action to make sure it fills and dispenses completely. Run background counts until acceptable results are obtained for all background parameters.
13. Confirm calibration by running controls before running patient samples.
14. Record this maintenance in your maintenance log.

Sample Syringe Cleaning/Replacement

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Large basin of deionized water at room temperature
5. Deionized water
6. 7/64" Allen wrench (Accessory Kit)

WARNING: **Potential Biohazard.** Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

1. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
2. Press **[MORE]** followed by **[CLN SAMPL SYRINGE]**.
3. Locate and loosen the Allen screw four turns (using a 7/64" Allen wrench). Refer to the following figure or to the picture on the screen.

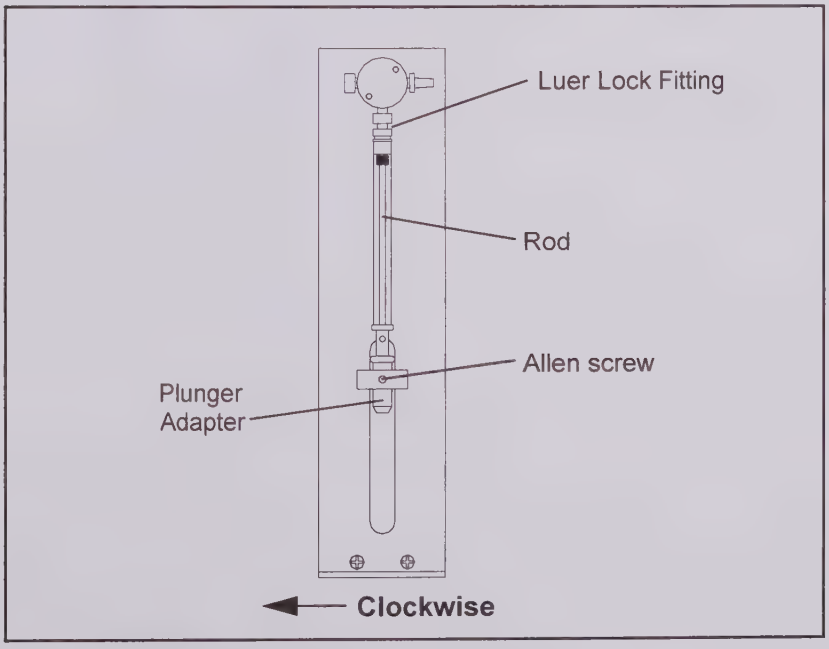


Figure 9.4: Sample Syringe

4. Press **[SYRINGE DOWN]**.
5. When the syringe comes to a stop, gently push up on the plunger until it clears the Drive Ring.
6. Unscrew the barrel of the syringe by turning the entire syringe clockwise (when viewed from above). Pull down to remove the syringe.
7. If there are saline crystals around the Luer lock fitting of the syringe, soak the entire syringe in deionized water for five minutes. Then, gently pull the plunger rod completely out of the barrel and allow both pieces to soak for a few minutes.

CAUTION: Do not touch the tip of the plunger with your hands. Do not pull or push the plunger when it is dry.

8. Rinse the syringe in clean deionized water. Insert the plunger into the barrel of the syringe and push it all the way forward. If the syringe needs to be replaced, a new syringe may be installed.

   NOTE: Before installing a new Sample Syringe, remove the plunger adapter by unscrewing it (clockwise) from the bottom of the plunger. Note the location of the split lockwasher and ensure it is in place when reinstalling the new syringe. Screw the plunger adapter from the old syringe into the new syringe.

9. Draw deionized water into the syringe so that the entire syringe is filled and the plunger is withdrawn as far as possible.
10. Push the plunger in all the way. Reinstall the syringe into the luer lock fitting by turning the barrel counterclockwise (when viewed from above) to finger-tight. *Do not overtighten.*
11. Push the plunger adapter into the Drive Ring hole, then press **[RESTORE SYRINGE]**. Adjust the position of the plunger adapter so that the white plunger head is slightly touching the top of the glass barrel.
12. Tighten the Allen screw using a 7/64" Allen wrench. *Do not overtighten.*
13. Press **[MAIN]** followed by **[RUN]** to display the **RUN** menu.
14. Press **[SPECIMEN TYPE]** followed by **[NORMAL BACKGRND]**.
15. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.

16. Confirm calibration by running controls before running patient samples.
17. Record this maintenance in your maintenance log.

Lyse Syringe Cleaning/Replacement

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Large basin of deionized water at room temperature
5. Deionized water
6. 7/64" Allen wrench (Accessory Kit)

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

1. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
2. Press **[MORE]** followed by **[CLN LYSE SYRINGE]**. The syringe plunger moves up.
3. Locate and loosen the Allen screw four turns (use a 7/64" Allen wrench). Refer to the following figure or to the picture on the screen.

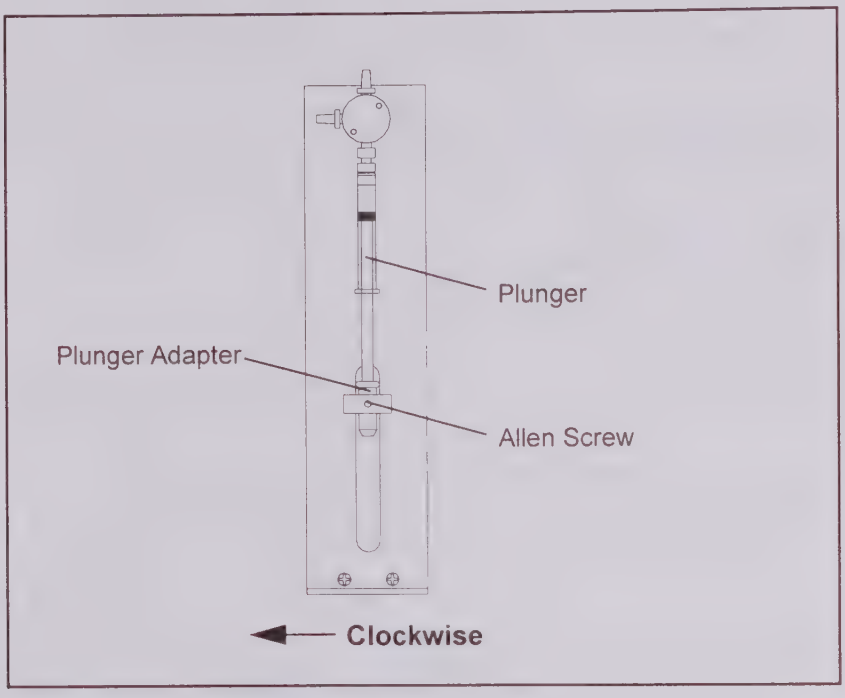


Figure 9.5: Lyse Syringe

4. Press **[SYRINGE DOWN]**.
5. When the syringe comes to a stop, gently push up on the plunger until it clears the Drive Ring.
6. Unscrew the barrel of the syringe by turning the entire syringe clockwise (when viewed from above). Pull down to remove the syringe.
7. Immerse the syringe in the basin of deionized water prepared earlier. Allow the syringe to soak for one to two minutes to dissolve any accumulated salt deposits. If the syringe needs to be replaced, a new syringe may be installed.

   NOTE: Before installing a new Lyse Syringe, remove the Plunger Adapter by unscrewing it (clockwise) from the bottom of the plunger. Note the location of the split lockwasher and ensure it is in place when reinstalling the new syringe. Screw the Plunger Adapter from the old syringe into the new syringe.

8. While the syringe is still immersed, remove the plunger from the barrel. Allow the syringe and plunger to soak for five minutes.

CAUTION: Do not pull or push the plunger when it is dry.

9. Remove the plunger and syringe from the basin and thoroughly rinse each with clean deionized water.
10. Reassemble the syringe by inserting the plunger all the way into the barrel.
11. Reinstall the syringe into the luer lock fitting by turning it counterclockwise (when viewed from above). *Do not overtighten.*
12. Press **[SYRINGE UP]**.
13. Guide the syringe plunger through the Drive Ring as the Drive Ring moves up. Adjust the position of the plunger adapter so that the white plunger head is slightly touching the top of the glass barrel. Tighten the Allen screw using a 7/64" Allen wrench. *Do not overtighten.*
14. Press **[RESTORE SYRINGE]**.
15. Press **[MAIN]** followed by **[RUN]** to display the **RUN** menu.
16. Press **[SPECIMEN TYPE]** followed by **[NORMAL BACKGRND]**.
17. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
18. Confirm calibration by running controls before running patient samples.
19. Record this maintenance in your maintenance log.

NOTES

Sample Aspiration Probe Interior Cleaning

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Syringe (10 cc or larger)
5. Sample Cup
6. Deionized water
7. Cleaning solution (5 mL of 5% filtered bleach added to 5 mL of water)

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS].
2. Press [MORE] followed by [PROBE HOME].
3. Remove the Upper Front Cover and press [PROBE DOWN]. (For instructions on removing the Upper Front Cover, refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Flow Panel Inspection and Installation, Upper Front Cover Removal.*** For the 1700CS, refer to **Section 13: *CELL-DYN 1700CS — Closed Sample Aspiration,* Subsection: *Installation, Upper Front Cover Removal.)***

   CAUTION: Moving the probe while performing this procedure may require Reinitialization.

4. Locate the silicone tubing attached to the top of the Sample Aspiration Probe. (Refer to the following figure.) Hold the 1/32" Tubing and carefully pull up on the 1/16" Straight Connector until it is free of the short tubing which remains attached to the top of the probe.

   NOTE: Do not loosen the Probe Alignment Guide.

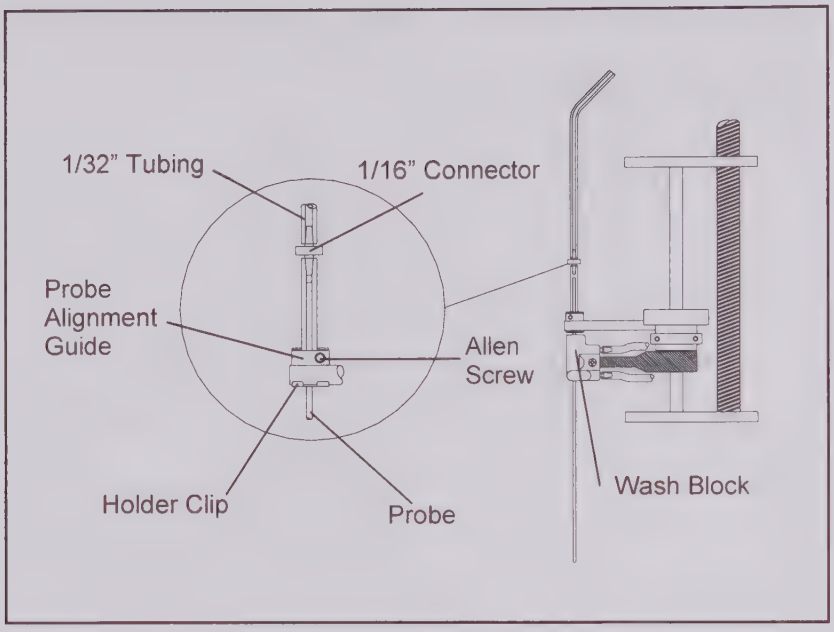


Figure 9.6: Sample Aspiration Probe Assembly

5. Place a Sample Cup beneath the probe to catch the rinse solution.
6. Fill a syringe with the cleaning solution prepared earlier. Insert the tip of the syringe into the tubing at the top of the Aspiration Probe and inject the solution to flush the probe.
7. Fill the same syringe with deionized water and inject the water into the Sample Probe from the top to rinse the probe. Repeat the procedure three times to thoroughly rinse the probe.
8. Hold the 1/32" silicone tubing to steady it and insert the 1/16" straight connector completely into the 1/32" silicone tubing.
9. Press **[PROBE HOME]**.
10. Reattach the Upper Front Cover and press **[PROBE DOWN]**.
11. Press **[MAIN]** to return to the **MAIN MENU**.
12. Press **[RUN]** followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**.
13. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
14. Record this maintenance in your maintenance log.

HGB Flow Cell Manual Cleaning

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Syringe (10 to 20 cc with at least 3" long silicone tubing attached to tip)
5. Cleaning solution (equal parts of 5% filtered bleach and water)
6. Wire solenoid valve-puller
7. Deionized water

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS].
2. Press [MORE].
3. Press [PROBE HOME].
4. Remove the Upper and Lower Front Covers from the instrument. (For instructions on removing the Upper and Lower Front Covers, refer to ***Upper Front Cover Removal*** and ***Lower Front Cover Removal*** within **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Flow Panel Inspection and Installation.*** For the 1700CS, refer to ***Upper Front Cover Removal*** and ***Lower Cover Removal*** within **Section 13: *CELL-DYN 1700CS — Closed Sample Aspiration,* Subsection: *Installation.)***
5. Fill the syringe with the cleaning solution prepared earlier.
6. Attach the wire puller to Pinch Valve 26 (refer to the following figure).
7. Locate the HGB Flow Cell (refer to the following figure) and trace the bottom black tubing ending at the T-fitting.

   NOTE: Do not attempt to remove the black tubing.

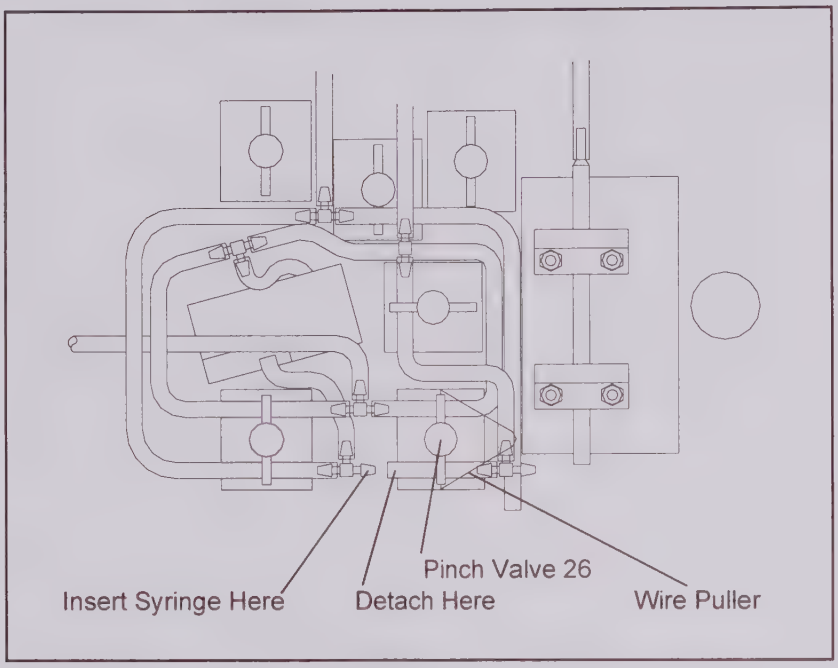


Figure 9.7: HGB Flow Cell

8. Disconnect the tubing on the right side of the T-fitting and attach the syringe tubing to the open end of the T-fitting.
9. Pull Pinch Valve 26 open and hold open while injecting between 5 and 10 cc of the solution into the flow cell.
10. Still keeping Pinch Valve 26 open, move the syringe plunger in and out several times to ensure optimum rinsing action. Release the wire, allowing Pinch Valve 26 to close. Leave the solution in the flow cell for three to five minutes.
11. Remove the syringe from the T-fitting.
12. Drain the solution from the flow cell by pulling open Pinch Valve 26.
13. Remove any cleaning solution from the syringe and fill it with deionized water.
14. Perform the same syringe injection procedure (steps 8 through 10) to flush out the cleaning solution thoroughly.
15. Remove the syringe from the T-fitting and reattach Pinch Valve 26 tubing to the T-fitting. Make sure the tubing is securely attached.
16. Remove the wire puller from Pinch Valve 26.

17. Reattach first the Lower Front Cover then the Upper Front Cover.
18. Press [PROBE DOWN].
19. Press [MAIN] to return to the MAIN MENU.
20. Press [RUN] followed by [CLEAR ORIFICE] to prime detergent back into the HGB Flow Cell. Press [SPECIMEN TYPE] and [NORMAL BACKGRND].
21. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
22. Record this maintenance in your maintenance log.

Vent Line Cleaning

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Two small beakers
5. Deionized water

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

1. Locate the vent lines on either side of the Flow Panel and follow the lines to their ends. Both lines will have open ends. Refer to the following figure.

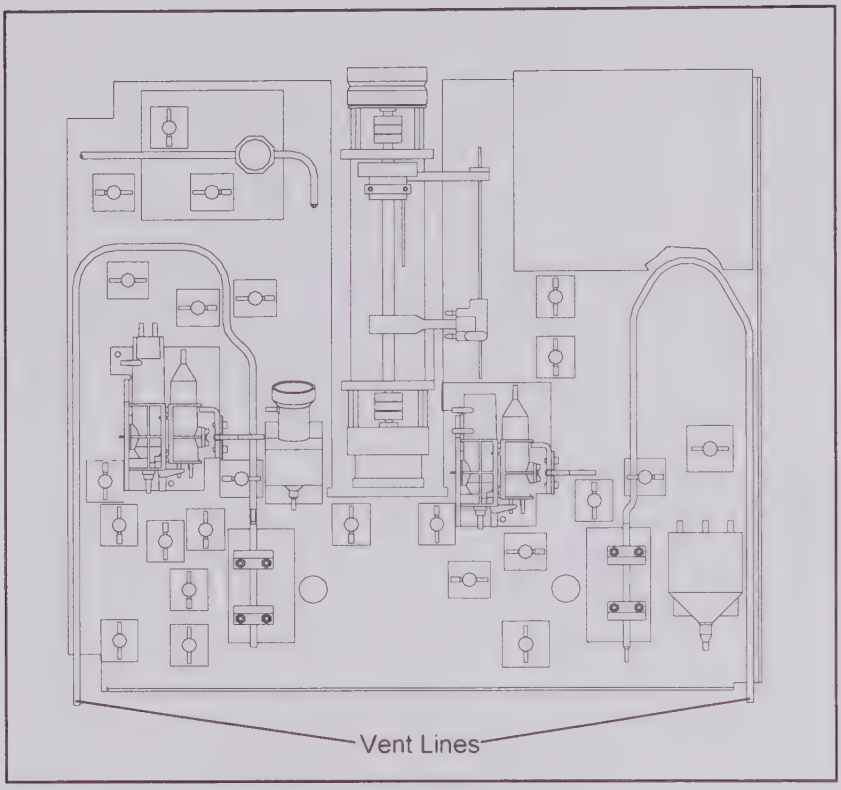


Figure 9.8: Front Panel Vent Lines

2. Immerse the end of each line in a beaker of deionized water.
3. In the **MAIN MENU**, press **[RUN]** followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**.
4. Press the Touch Plate to run a background count. Run a second background count. Ignore any **FLOW ERROR** or **CLOG** messages.
5. Remove the lines from the water, then remove the beakers.
6. Run two background counts to clear out the water from the vent lines.
7. Record this maintenance in your maintenance log.

Vacuum Accumulator Draining and Cleaning

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Large syringe
5. Large beaker
6. Deionized water

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure to Check for Liquid

1. Turn the instrument OFF.
2. Locate the end of the accumulator tubing next to the Reagent Inlet Panel on the lower left side of the instrument. Refer to the following figure.

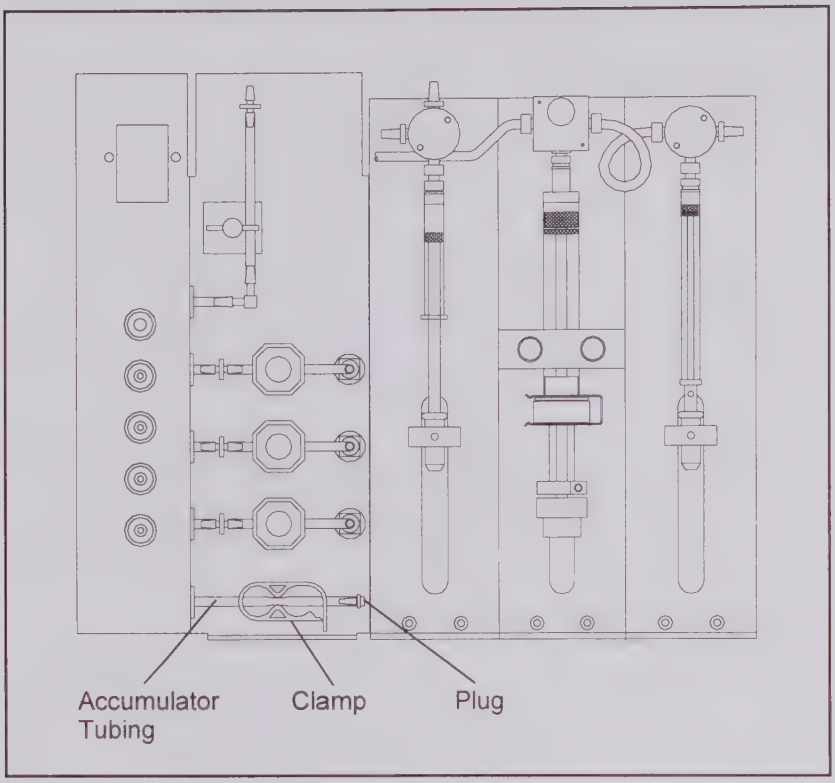


Figure 9.9: Left Side Panel

3. Carefully pull the tubing and Clamp free of the Analyzer frame. Pull the Plug from the end of the tubing and set the plug aside.
4. Place the tip of an empty syringe in the end of the tubing and remove the Clamp. Aspirate the syringe to draw any liquid in the accumulator into the syringe.
5. If there is no evidence of liquid, it is not necessary to clean the Vacuum Accumulator unless you are troubleshooting a high platelet background. Remove the syringe, replace the Clamp and Plug, and put the tubing back inside the Analyzer Frame.

Procedure to Drain and Clean the Accumulator

1. Perform the previous procedure.
2. If evidence of liquid is found, replace the Clamp on the tubing and remove the syringe. Place the end of the tubing in an empty beaker.

3. Remove the Clamp on the tubing and allow the Accumulator to completely drain into an empty beaker.
4. Use an empty syringe to aspirate any remaining fluid from the tubing.
5. Fill a large empty syringe with deionized water. A 60-cc or larger syringe is recommended. Insert the tip of the syringe into the end of the Accumulator Tubing and inject deionized water into the Accumulator. Reclamp the tubing before removing the syringe.
6. Repeat step 4 until the Accumulator has been filled with 400 to 500 cc of deionized water.
7. Allow the Accumulator to soak with deionized water for two to five minutes.
8. Place the end of the tubing in a large empty beaker. Remove the clamp on the tubing and allow the Accumulator to completely drain into the beaker.
9. Use an empty syringe to aspirate any remaining water from the Accumulator.
10. Fasten the clamp and reinsert the plug into the end of the tubing. Carefully put the tubing with clamp back inside the Analyzer Frame.
11. Turn the instrument ON. Wait for the instrument to Initialize. Press **[PRIME/RUN]** to prime the system.
12. In the **RUN** menu, press **[SPECIMEN TYPE]** followed by **[NORMAL BACKGRND]**.
13. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
14. Record this maintenance in your maintenance log.

Aspiration Probe Removal and Replacement

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Replacement probe
5. 3/32" Allen wrench

WARNING: Potential Biohazard. The probe is sharp and potentially contaminated with infectious materials. Avoid any contact with the probe. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Procedure

1. In the SPECIAL PROTOCOLS menu, press [MORE] followed by [PROBE HOME]. Remove the Upper Front Cover, then press [PROBE DOWN].

CAUTION: Moving the probe while performing this procedure may require Reinitialization.

2. Locate the silicone tubing attached to the top of the Sample Aspiration Probe. (Refer to Figure 9.6, Sample Aspiration Probe Assembly.) Hold the probe and pull the short 1/32" Tubing (attached to the top of the probe) up until it is free of the metal probe. The 1/16" Straight Connector should still be attached to the short tubing.
3. Remove the Probe Holder Clip.

CAUTION: Do not loosen the Allen screw on the Probe Alignment Guide. The Alignment Guide determines the proper probe alignment and is Factory Set. Also, do not loosen the Allen screw in the Alignment Guide of the replacement probe.

4. Grasp the probe at the top and pull it up until it is free of the Wash Block.

   NOTE: If the probe is bent or unable to be removed from the top, hold the probe to steady it while using a 3/32" Allen wrench to loosen the Allen screw on the Probe Alignment Guide. Slide the Probe Alignment Guide up and off the top of the probe. Pull down on the probe until it is free of the Wash Block.

5. Insert the new probe from the top into the probe holder and Wash Block. Push the probe down until the Probe Alignment Guide comes to rest on the Probe Holder.
6. With the Probe Alignment Guide flush with the Probe Holder, reinstall the Probe Holder Clip with the two curved tips under the Probe Holder Bar.
7. Hold the probe to steady it and insert the 1/32" Silicone Tubing onto the top of the Aspiration Probe.
8. Reattach the Upper Front Cover.
9. In the **MAIN MENU**, press **[RUN]** followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**.
10. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
11. Record this maintenance in your maintenance log.

Fuse Replacement

Materials Required

1. Flathead screwdriver

Procedure

There are two conditions under which a fuse should be replaced: if the fuse has failed, or if the power setting is changed from 110/120 VAC to 220/240 VAC or vice versa.

WARNING: Electrical Shock Hazard. Always turn the system OFF and disconnect the power cord before checking or changing the fuse.

1. Insert a flathead screwdriver into the Fuse Holder Slot on the Rear Panel of the system.
2. Push in and turn the Fuse Holder counterclockwise to remove it.

3. Pull the fuse to remove it from the holder.
4. Check the fuse. If it has obviously failed, replace it. If it has not failed, verify that it is the correct type of fuse. For a description of the correct fuses, refer to **Section 1:** ***Use or Function,*** **Subsection:** ***System Components, Analyzer, Rear Panel, Fuse.***

   NOTE: If you are not sure if the fuse has failed, replace it and see if the problem is corrected.

5. Insert the fuse completely into the Fuse Holder and replace the holder.
6. Insert a flathead screwdriver into the Fuse Holder Slot and push in and turn clockwise to lock it in place.
7. Reconnect the power cord and turn the system ON.

CAUTION: The unit must be turned OFF and unplugged prior to replacement. If failure reoccurs, turn the unit OFF, unplug the unit, and call the Abbott Customer Support Center.

Preparing the Analyzer for an Extended Period of Non-Use or for Shipping

Materials Required

1. Gloves
2. Lab coat
3. Safety glasses
4. Deionized water
5. Cardboard Disk Drive Protector
6. Disinfectant (cleaning solution); 10% solution of filtered bleach (in deionized water)
7. Large beaker
8. Plastic bag

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Procedure

Salt deposits and reagent residue may damage the flow system if not removed before the CELL-DYN 1700 System is stored (idle for two weeks or longer) or shipped.

1. In the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
2. Press **[MORE]** twice.
3. Press **[CLEAN FOR SHIPPING]**. The prompt screen is displayed.

   NOTE: Press the asterisk (*) key on the PC or Membrane Keyboard to cancel this procedure and return to the **SPECIAL PROTOCOLS** menu.

4. Follow the screen prompts to rinse the Flow System with deionized water.
5. Follow the screen prompts to purge water from the Flow System.
6. Turn the power OFF.
7. Carefully remove the tubing from the Normally Closed (black octagon) Valve located on the upper left portion of the Flow Panel.
8. Remove the Diluent, Lyse, and Detergent Inlet Tubing from their Normally Closed (black octagon) Valves located on the lower left side of the Analyzer.
9. Remove all four tubing lines and the Waste Sensor Line from their fittings on the lower left side of the Analyzer. The Waste Line should be emptied and rinsed with disinfectant. Place each length of tubing in a separate protective plastic bag and close it. (Keep the Waste Line and Waste Sensor Line together.) Place the bags in the Accessory Kit. Wipe the surface of the instrument with disinfectant.

   NOTE: Keep all tubing lines clean to prevent contamination.

10. Insert the cardboard Disk Drive Protector into the Floppy Disk Drive (after removing any floppy disk).
11. Remove the Power Cord from its connector on the Rear Panel and from the outlet receptacle. Place the cord in the Accessory Kit.

NOTES

CELL-DYN Logbook

Abbott suggests that you create a logbook for the instrument. This logbook should contain all necessary calibration documentation and other information that is pertinent to your instrument. Suggested sections that you may want to include in the logbook are:

- Laboratory Operating Procedures
- Quality Control
- Calibration
- Maintenance
- Troubleshooting
- Problem Resolution
- Service Calls
- Installation Documentation
- Software Upgrades
- Reagent Lot Number Changes

This logbook should be stored near the instrument and be accessible to all operators and Abbott Service Personnel.

NOTES

Preventive Maintenance Log for CELL-DYN 1700

Instructions:

1. Keep these sheets as a master copy.
2. Enter appropriate month and year.
3. Check off performance and initial in appropriate day.

Year ____ Month ____

	Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Start-Up	Check Reagent Levels																															
	Check Printer Paper																															
	Check Tubing in NC Valves																															
	Run Background Count																															
	Run Controls																															
Daily Shutdown	Daily Shutdown																															
	Empty Waste (as needed)																															
Weekly	Open Sample Auto-Clean																															
	Aspiration Probe Exterior																															
	CS Auto-Clean (CS models only)																															
	CS Tube Holder Well (CS models only)																															
Monthly	Lyse Inlet Tubing Rinse																															
	Rear Fan Filter																															
Semi-annually	Printer Cleaning																															

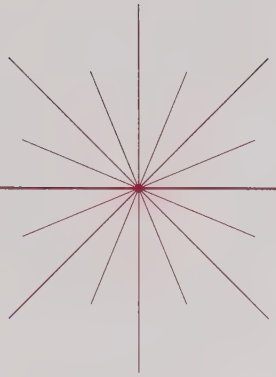
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Day																															

Year Month

	Day																														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Aperture Plates Cleaning																															
Diluent Syringe Cleaning																															
Diluent Syringe Replacement																															
Sample Syringe Cleaning/ Replacement																															
Lyse Syringe Cleaning/ Replacement																															
Sample Aspiration Probe Interior Cleaning																															
HGB Flow Cell Manual Cleaning																															
As Required																															
Vent Line Cleaning																															
Vacuum Accumulator Draining & Cleaning																															
Aspiration Probe Removal & Replacement																															
Prolonged Shutdown																															
Prepare for Extended Non-Use or Shipping																															
Fuse Replacement																															
Peristaltic Pump Tubing Replacement (CS models only)																															
Calibrate as Needed																															

ABBOTT

CELL-DYN® 1700 SYSTEM



Troubleshooting and Diagnostics

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Troubleshooting and Diagnostics

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NOTES

Overview

This section gives instructions for identifying, troubleshooting, and correcting instrument problems. The CELL-DYN® 1700 System continuously monitors the status of the system and displays pertinent information in the Status Box. If a problem is detected within the system, the Status Box displays a message such as **Lyse Empty**, **Waste Full**, or **Clog**. If a problem with the hardware occurs, the message **Not Ready: See Diagnostics** is displayed.

The following ***Diagnostics*** subsection discusses the **DIAGNOSTICS** menu soft keys. The remainder of this section is devoted to the ***Troubleshooting Guide***.

NOTES

Diagnostics

The main functions of the **DIAGNOSTICS** menu are to do the following:

1. Check the system and fault status, identifying operator-correctable and service-correctable faults
2. Perform diagnostics tests for troubleshooting and service
3. Display and print data for troubleshooting and service

This subsection describes the keypad labels available from the four **DIAGNOSTICS** menu screens when the instrument is Initialized and Primed. These keys enable the operator or service representative to obtain information and execute programs that assist in troubleshooting and to identify corrective action.

When some keys are pressed, the message **FOR SERVICE USE ONLY** is displayed. The data these keys provide are meaningful only to trained Abbott Field Service Representatives and are not useful to the operator. If these keys are pressed inadvertently, the system may have to be reinitialized.

In the **MAIN MENU**, press **[DIAGNOSTICS]** to display the main **DIAGNOSTICS** menu. The **DIAGNOSTICS** menu has the following keys:

[INITIALIZATION]
[RAW DATA]
[COUNT TEST]
[MORE]
[PRINTER OUTPUT]
[HELP/ERROR]
[MAIN]

Each of these keys is described below.

Initialization

[INITIALIZATION] is used to perform an Initialization cycle. In the process, all motors are first run through their "home" positions and all circuitry is checked. When the cycle is completed, the system is Initialized. **[PRIME/RUN]** must be pressed to bring the instrument to the READY state.

Raw Data

[RAW DATA] is used to display the raw measurement data for the last specimen analyzed.

Count Test

[COUNT TEST] is used to run specimens and display count check data without returning to the RUN menu. This key changes to [PRE-DIL TEST] when Pre-Dilute Mode has been selected, and to [ELEC BKGD TEST] when Electrical Background has been selected as the specimen type. The prompt PRESS CLOSED OR OPEN SAMPLE SWITCH WHEN READY or PRESS ASTERISK TO CANCEL THIS FUNCTION is displayed in the upper left corner of the screen. Coded data relating to specific cycle functions, raw measurement, and flow count time are displayed for use in troubleshooting or service.

More

[MORE] displays a new menu and new soft keys that allow the operator to perform additional diagnostics to assist in troubleshooting. This key performs the same function on all diagnostics menus.

Printer Output

[PRINTER OUTPUT] allows the operator to print any screen to the Graphics Printer by turning the printer output ON. No printing occurs at this point; printing occurs only when another key, such as [RAW DATA] or [WBC HISTOGRAM], is pressed.

When [PRINTER OUTPUT] is pressed, the key is highlighted (white on dark blue), indicating that printer output is ON. Data will be displayed on the screen and printed on the Graphics Printer.

When pressed again, the key returns to its original (white on cyan) format, indicating that printer output is OFF. Data will only be displayed on the screen. The current printer status is displayed in the upper left section of the screen. This key performs the same function on all diagnostics menus.

Help/Error

[HELP/ERROR] accesses a screen with a [FAULT LOG] key and a [HELP] key. The [FAULT LOG] key allows the operator to view up to 16 errors including any pending fault. Pressing [HELP] allows the operator to view help messages. The [HELP/ERROR] key is available on each screen.

If a fault is pending and **[HELP/ERROR]** is pressed, the Fault Log is automatically displayed. There are three major types of fault messages of concern to the operator:

- Data Invalidating Faults (DIF) — sample-dependent conditions such as Clog, Flow Error, Count Overrange, etc.
- Device Faults (DEV) — system device faults such as Printer Out-of-Paper, RS-232 Comm Error, etc.
- Field Service Faults (FSF) — serious faults that may require Abbott Customer Support. They are mechanical, flow, or electronic faults which will stop the instrument from completing a procedure. The message **Not Ready: See Diagnostics** is also displayed in the Status Box of the menu in which the fault occurred.

When the **Not Ready: See Diagnostics** message is displayed, additional information about a pending fault can be obtained as follows:

- Go to the **MAIN MENU** and press **[DIAGNOSTICS]** to access the **DIAGNOSTICS** menu. The fault information will be displayed immediately.

Main

[MAIN] takes the operator back to the **MAIN MENU** and performs the same function on all diagnostics menus.

More

When **[MORE]** is pressed in this submenu, the second of four **DIAGNOSTICS** menu screens is displayed. The following keys may be selected:

[WBC HISTOGRAM]
[RBC HISTOGRAM]
[PLT HISTOGRAM]
[SMOOTHING OFF] / [SMOOTHING ON]
[MORE]
[PRINTER OUTPUT]
[HELP/ERROR]
[MAIN]

These soft keys are described below.

WBC Histogram

[WBC HISTOGRAM] is used to display the lysate-modified white cell count (numeric) data accumulated in each of 256 size channels. Each line contains data for 16 channels. For example, line one data is for channels 1 to 16, line two data is for channels 17 to 32, etc. Each size channel equals 1.758 femtoliters.

RBC Histogram

[RBC HISTOGRAM] is used to display the red blood cell count (numeric) data accumulated in each of 256 size channels. Each line contains data for 16 channels. For example, line one data is for channels 1 to 16, line two data is for channels 17 to 32, etc. Each size channel equals 1 femtoliter.

PLT Histogram

[PLT HISTOGRAM] is used to display the platelet count (numeric) data accumulated in each of 256 size channels. Each line contains data for 16 channels. For example, line one data is for channels 1 to 16, line two data is for channels 17 to 32, etc. Each size channel equals 0.1367 femtoliters.

> NOTE: All three histograms are displayed and printed as numeric data only.

Smoothing Off/On

This key toggles between [SMOOTHING OFF] and [SMOOTHING ON]. This key is used to change the histogram display status. When smoothing is OFF and a histogram key is pressed, raw histogram data is shown. When smoothing is ON and a histogram key is pressed, normalized and threshold-edited histogram data is shown. The number of the peak channel is also shown.

More

When [MORE] is pressed in this submenu, the third of four DIAGNOSTICS menu screens is displayed.

The following keys may be selected:

[PROBE HOME]
[PROBE UP]
[MORE]
[PRINTER OUTPUT]
[HELP/ERROR]
[MAIN]

These soft keys are described below.

Probe Home

[PROBE HOME] is used to check the homing operation of the probe mechanism. When pressed, this key is highlighted and changes to [PROBE DOWN].

Probe Up

[PROBE UP] is used to check the up and down motion of the probe mechanism. When pressed, this key is highlighted and changes to [PROBE DOWN].

More

When [MORE] is pressed again, the fourth of four DIAGNOSTICS menu screens is displayed. The following keys may be selected:

[SYSTEM STATUS] / [CLEAR ALARM]
[FAULT REPORT]
[SERVICE HEX CODES]
[SERVICE DEC CODE]
[MORE]
[PRINTER OUTPUT]
[HELP/ERROR]
[MAIN]

These keys are described below.

System Status

[SYSTEM STATUS] displays or prints the current alarm status of the system.

Fault Report

[FAULT REPORT] displays a new screen that allows the operator or service personnel to review or print the current fault status. Whenever the message **Not Ready: See Diagnostics** is displayed in the System Status Box, it is directing the operator to go to the DIAGNOSTICS menu and press this key.

Service Hex Codes

This screen is not for operator use. It is for Service Personnel only.

Service Dec Code

This screen is not for operator use. It is for Service Personnel only.

More

When [MORE] is pressed in this submenu, the main DIAGNOSTICS menu is displayed.

Troubleshooting

The ***Troubleshooting Guide*** later in this section is designed to assist the operator in identifying and resolving instrument problems. Instructions are also given for obtaining technical assistance from the Abbott Customer Support Center.

This ***Troubleshooting Guide*** lists the most common problems encountered with the CELL-DYN 1700 System along with their probable causes and recommended corrective action.

> **NOTE:** Generally, conditions that are instrument- or reagent-related will occur on all samples, including controls. Therefore, it is important to confirm instrument performance by rerunning controls and/or additional patient specimens.

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Overview

Good troubleshooting skills are learned by using a logical, step-by-step approach to problem solving. The first step in the process is understanding normal instrument operation and preventive maintenance. A good, working knowledge of the instrument is essential for identifying and resolving operational problems. Logical troubleshooting may be divided into three steps:

1. Problem Identification
2. Problem Isolation
3. Corrective Action

Step 1, Problem Identification, is not only identifying what is wrong but also noting what is right. The investigation should identify the problem area and eliminate areas that are working correctly. Once this is done, the troubleshooting process moves quickly to the next step.

Step 2, Problem Isolation, further classifies the problem. Instrument problems are generally divided into three categories:

- Hardware component related
- Software computer program related
- Measurement related to sample analysis

Typically, hardware and software problems are corrected by an Abbott-authorized Service Representative. Measurement problems are generally operator-correctable and are further subdivided into problems related to sample handling, maintenance, or calibration.

Step 3, Corrective Action, involves taking appropriate action to correct the problem. If the operator can correct the problem, with or without technical assistance, normal operation can quickly resume.

The following ***Troubleshooting Guide*** is designed to enhance the troubleshooting process by providing information to assist in problem identification, isolation, and corrective action.

Obtaining Technical Assistance

Technical assistance is obtained by calling the Abbott Customer Support Center. It is important to provide the Customer Support Specialist with a clear and detailed description of the problem. When assistance is needed, please be prepared to provide the following information for the Customer Support Specialist:

1. Instrument model number.
2. Serial number of the Analyzer and software version in use.
3. Description of the problem. (Whenever possible, print the Fault Status Report obtainable from the **DIAGNOSTICS** menu screen.)
4. The lot numbers and expiration dates of the CELL-DYN Reagents and Controls currently in use.
5. Sufficient examples of data to facilitate the discussion.

Customer Support

United States: 1 (800) CELL DYN or 1 (800) 235-5396

Abbott Diagnostics Customer Support Center:
5440 Patrick Henry Drive
Santa Clara, CA 95054

Canada: 1 (800) 387-8378

International: Call your local customer support representative.

NOTES

Index of Error Messages and Conditions

This index lists all the messages and conditions that are described in the following ***Troubleshooting Guide***.

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NOTES

Troubleshooting Guide

> > > > appear in place of the result for WBC, RBC, or PLT.

Probable Cause(s)	Corrective Action
Data exceed linear range for that parameter.	• For RBC or PLT: Dilute a 0.5-mL aliquot of well-mixed whole blood with 0.5 mL diluent (1:2 ratio). Close the container and invert it 10 to 15 times to mix. Run the specimen as usual. Multiply the RBC, HGB, HCT, and PLT result by 2 to obtain a reportable value. • For WBC: Dilute a 0.5-mL aliquot of well-mixed whole blood with 0.5 mL of diluent (1:2 ratio) or 1 mL (1:3), 1.5 mL (1:4), or 4.5 mL (1:10) of diluent as required. Close the container and invert it 10 to 15 times to mix. Run this specimen as usual. Multiply each WBC and PLT result by 2, 3, 4, or 10 (per ratio of diluent to blood used above) to obtain a reportable value.
Improper reagent delivery or sample aspiration.	• Inspect syringes for proper operation. • Check Reagent Inlet Lines for crimping.

Abnormal or erratic HGB, MCH, and/or MCHC results.

Probable Cause(s)	Corrective Action
Dirty HGB Flow Cell (HGB Raw Data Ref. reading < 1700).	Perform the Hemoglobin Flow Cell Manual Cleaning Procedure as described in **Section 9: *Service and Maintenance*, Subsection: *Nonscheduled Maintenance Procedures, HGB Flow Cell Manual Cleaning.***
Lipemic sample or sample with WBC count above 50,000/µL.	Specimen exceeds limitations of the procedure. Retest according to your standard laboratory operating procedure.
Circuitry malfunction.	Go to the **DIAGNOSTICS** menu and press **[PRINTER OUTPUT]**. Press **[RAW DATA]**. Data will display and print. Check the results for Hemoglobin Error, Hemoglobin Sample, and HGB Reference. Obtain technical assistance as required.

Abnormal printing conditions.

Probable Cause(s)	Corrective Action
Printer malfunction.	For assistance call the Abbott Customer Support Center.

Background data are unacceptable.

Probable Cause(s)	Corrective Action
Interference from other electrical devices.	Use dedicated power source or line voltage regulator; relocate instrument to an area free from interfering devices. Press **[RUN]**, **[SPECIMEN TYPE]**, and **[ELECTRICL BACKGRND]**. Run background count. If clear, go to next probable cause. If high, obtain technical assistance.
Cold reagents — less than 59°F (15°C).	Allow reagents to warm. Rerun background check. If the background data is not acceptable, go to the next probable cause.
Dirty transducer and/or aperture.	Perform the Auto-Clean Procedure described in **Section 9: *Service and Maintenance,* Subsection: *Weekly Maintenance Procedures.***
Contaminated diluent or detergent.	Perform the cleaning procedures outlined in **Section 9: *Service and Maintenance* Subsection: *Nonscheduled Maintenance Procedures, Preparing the Analyzer for an Extended Period of Non-Use or for Shipping.*** Use a 25% ratio of filtered bleach to water for cleaning and disinfecting the flow system. Repeat the procedure using distilled water. Rinse and refill the flow system with freshly opened containers of diluent and detergent.
Contaminated lyse (WBC background only).	Install a freshly opened container of lyse. Perform the Lyse Syringe Cleaning and Lyse Inlet Tubing Rinse Procedures described in **Section 9: *Service and Maintenance.*** Prime the system with lyse.
Diluent frozen in shipment.	Replace with a new lot number or different shipment.
Vacuum Accumulator contaminated.	Clean the Vacuum Accumulator, as described in **Section 9: *Service and Maintenance,* Subsection: *Nonscheduled Maintenance Procedures, Vacuum Accumulator Draining and Cleaning.***

The message CLOG is displayed in place of Count Time.

Probable Cause(s)	Corrective Action
Debris, fibrin clots, or protein buildup is restricting fluid flow through the aperture.	Press [CLEAR ORIFICE] to backflush the aperture and reset the maximum count time. If the situation occurs repeatedly, go to the SPECIAL PROTOCOLS menu and run the Auto-Clean Procedure. Perform manual aperture cleaning. Check the sample for fibrin clots or red blood cell agglutination. Redraw the specimen as required. Rerun the specimen if required.
Flow system blockage resulting from pinched tubing in the Diluent or Detergent Normally Closed Valves, or reagent particles may be in the Flow Panel.	Remove the tubing in the Diluent and Detergent Normally Closed Valves, massage the tubing to remove any crimps, then reseat the tubing in the valve. Check Diluent Syringe installation. If the situation occurs repeatedly, perform the maintenance procedures to prepare the unit for shipping. (Refer to **Section 9: *Service and Maintenance,* Subsection: *Nonscheduled Maintenance Procedures, Preparing the Analyzer for an Extended Period of Non-Use or for Shipping.***) Use a 25% ratio of filtered bleach to water.

The message DETERGENT EMPTY is displayed.

Probable Cause(s)	Corrective Action
Detergent container is empty.	Install a fresh container of detergent. Press [CLEAR ALARM]. Run a background count.
Reagent with a different conductivity was installed.	Install only Abbott-recommended reagents as noted in **Section 1:** ***Use or Function,*** **Subsection:** ***System Components, Reagent System.*** **NOTE:** Stated performance does not apply when other reagents are installed.
Detergent is not being pulled into flow system.	Remove the tubing from the Detergent Normally Closed Valve, massage the tubing to remove any crimps, then reseat the tubing. (Refer to **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***Installation, Tubing and Diluent Syringe Installation.)*** Check for crimps in the detergent line from inside the detergent container to the Reagent Inlet Panel. Press [CLEAR ALARM].

The message DILUENT EMPTY is displayed.

Probable Cause(s)	Corrective Action
Diluent container is empty.	Install a fresh container of diluent. Press [CLEAR ALARM]. Run a background count.
Reagent with different conductivity was installed.	Install only Abbott-recommended reagents as described in **Section 1:** ***Use or Function,*** **Subsection:** ***System Components, Reagent System.*** Press [CLEAR ALARM]. **NOTE:** Stated performance does not apply when other reagents are installed.
Diluent is not being pulled into flow system.	Remove the tubing from the Diluent Normally Closed Valve on the Flow Panel and from the Diluent Normally Closed Valve on the Left Side Panel next to the Reagent Inlet Panel. Massage the tubing to remove any crimps, then reseat the tubing. (Refer to **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***Flow Panel Inspection and Installation*** and **Subsection:** ***Tubing and Diluent Syringe Installation.)*** Check for crimps in the diluent line from inside the diluent container to the Reagent Inlet Panel. Press [CLEAR ALARM].
Diluent Syringe Clamp Nut has vibrated loose.	With one hand holding steady the Calibration Block, confirm that the large knurled Clamp Nut on the bottom of the syringe is fully tightened —if it is not, tighten it to finger-tight. Press [CLEAR ALARM].

The message FLOW ERR is displayed in place of Count Time.

Probable Cause(s)	Corrective Action
Air bubbles are trapped in the dilution baths.	Press **[CLEAR ORIFICE]** to backflush the aperture and reset the maximum count time. Rerun the specimen. If the situation occurs repeatedly, go to the **SPECIAL PROTOCOLS** menu and press **[MORE]** followed by **[DRAIN BATHS]** to drain the liquid from each transducer. When the process is complete, press **[REFILL BATHS]**. This process removes any bubbles trapped inside the transducers. Check the Diluent Syringe and the tubing in the Diluent Normally Closed Valve on the Flow Panel.
Normally Closed Valve tubing pinched or not seated properly.	Remove the tubing in the Normally Closed Valves on the Left Side Panel and in the Diluent Normally Closed Valve in the upper left corner of the Flow Panel. Massage the tubing to remove any crimps, then reseat the tubing in the valves.

The message FLOW ERR or CLOG is displayed in place of both Count Times (WBC/RBC).

Probable Cause(s)	Corrective Action
Aperture plates installed in wrong baths.	Check plate installation. Confirm that the aperture plate marked "R/P" is installed in the von Behrens RBC/PLT Transducer located to the right of the probe. Confirm that the aperture plate marked "WBC" is installed in the von Behrens WBC Transducer located to the left of the probe. If necessary, refer to **Section 9: *Service and Maintenance*, Subsection: *Nonscheduled Maintenance Procedures, Aperture Plates Cleaning*.**
Insufficient wetting of detergent reagent to form a good meniscus in the metering tube.	Remove the Upper and Lower Front Covers to gain access to the Flow Panel. Press the White Start Switch (which replaces the Touch Plate) below the Aspiration Probe. Observe fluid flow and meniscus formation in each metering tube. When meniscus formation is poor, perform the flow system rinsing procedures outlined in **Section 9: *Service and Maintenance*, Subsection: *Nonscheduled Maintenance Procedures, Preparing the Analyzer for an Extended Period of Non-Use or for Shipping*.** Use a 25% ratio of filtered bleach to water for cleaning and disinfecting the flow system. Repeat the procedure using distilled water. Rinse the tubing and install a freshly opened container of detergent. Obtain technical assistance as required.
Insufficient liquid in the transducer. Air is drawn through the aperture.	Remove the Upper Front Cover and open the Left Side Panel to gain access to the Flow Panel and Syringe Panel. Press the Touch Plate. Observe the action of the Diluent Syringe and the fluid flow in and out of each transducer. If the syringe action is not complete, perform the Diluent Syringe Cleaning Procedure described in **Section 9: *Service and Maintenance*, Subsection: *Nonscheduled Maintenance Procedures, Diluent Syringe Cleaning*.** Obtain technical assistance as required.
Flow system leak.	Check the system for leaks or cracks.

Damaged aperture.	Check the aperture under a microscope using a low-power objective lens with external light source. If damage is observed, obtain a replacement aperture plate. Confirm calibration after replacement.
Normally Closed Valve tubing pinched or not seated properly.	Remove the tubing from the Normally Closed Valves on the Left Side Panel and Front Panel, massage the tubing to remove any crimps, then reseat the tubing.

INITIALIZED.

Probable Cause(s)	Corrective Action
Power-On Initialization cycle was performed.	The unit is NOT yet Primed. To run specimens, press **[PRIME/RUN]**.

Keypad selection or entry not accepted.

Probable Cause(s)	Corrective Action
Computer busy performing a function that prevents screen label selection.	Refer to the screen for current status messages: counting, etc.
Data being transmitted to printer or computer.	None required.
Keypad entry not allowed for this screen.	None required.
Computer, keypad, and/or circuitry malfunction.	Turn the instrument power OFF. Wait 30 seconds. Turn the power back ON. If the situation is not corrected, obtain technical assistance.

The message LYSE EMPTY is displayed.

Probable Cause(s)	Corrective Action
Lyse container is empty.	Install a fresh container of lyse.
Reagent with different conductivity was installed.	Install only Abbott-recommended reagents as described in **Section 1: *Use or Function,* Subsection: *System Components, Reagent System.*** Press [CLEAR ALARM]. **NOTE:** Stated performance does not apply when other reagents are installed.
No liquid was detected by the Internal Lyse Sensor.	Confirm that the end of the lyse tubing is immersed in reagent. When the container is empty, replace it with a fresh container of lyse. Press [CLEAR ALARM]. Check the entire Lyse Inlet Tubing for crimps. Run a background count. **NOTE:** Never pour the reagent remaining in an old container into a freshly opened container.
Lyse Syringe not moving properly.	Perform the Lyse Syringe Cleaning Procedure described in **Section 9: *Service and Maintenance,* Subsection: *Nonscheduled Maintenance Procedures, Lyse Syringe Cleaning.*** Press [CLEAR ALARM].
Lyse not being pulled into the flow system.	Remove the tubing from the Lyse Normally Closed Valve, massage it to remove any crimps, then reseat the tubing. (Refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Tubing and Diluent Syringe Installation.)*** Press [CLEAR ALARM].
Lyse Inlet Tubing is clogged.	Perform the Lyse Inlet Tubing Rinse Procedure described in **Section 9: *Service and Maintenance,* Subsection: *Monthly Maintenance Procedures, Lyse Inlet Tubing Rinse.*** Press [CLEAR ALARM].

No power.

Probable Cause(s)	Corrective Action
Power cord is loose or not securely connected to the unit or wall socket.	Confirm that the power cord is inserted securely into both the Rear Panel Connector and the wall outlet(s). Confirm that the plug prongs are not bent.
Power Switch is OFF.	Turn the Power Switch to ON (located on the upper Right Side Panel).
No voltage or wrong voltage at the lab power receptacle.	Confirm that the fuse and circuit breaker at facility (site) are acceptable. Confirm that the instrument's Rear Panel Voltage Selector Switch and fuse are correct for the power provided.
Defective Power Switch.	Obtain technical assistance.
Instrument malfunction.	Obtain technical assistance.

No screen display.

Probable Cause(s)	Corrective Action
The screen brightness adjustment knob is turned down.	Turn the brightness knob clockwise to adjust brightness.
Incoming power fluctuation.	Turn the instrument power OFF, wait 30 seconds, turn power back ON.

No screen labels.

Probable Cause(s)	Corrective Action
Cycle in process but not complete.	None. Refer to the screen for current status.
Incomplete data entry.	To abandon the unfinished Operator Entry Process and redisplay the screen labels, press Enter.

The message NOT READY: SEE DIAGNOSTICS is displayed.

Probable Cause(s)	Corrective Action
Instrument hardware malfunction detected during routine operation or initialization.	From the **MAIN MENU**, press **[DIAGNOSTICS]**. Press **[HELP/ERROR]**. A message pertaining to the computer-detected malfunction is displayed with the required operator action. Obtain technical assistance as required.

QC specimen results exceed acceptable limits.

Probable Cause(s)	Corrective Action
Improper mixing or handling of the QC specimen.	Refer to **Section 11: *Quality Control*, Subsection: *Quality Control Guide*** for the proper handling of QC specimens.
Dilution error.	Rerun specimen. If the situation occurs again, perform the Auto-Clean Procedure described in **Section 9: *Service and Maintenance*, Subsection: *Weekly Maintenance Procedures*, *Open Sample Auto-Clean*** or ***Closed Sample Auto-Clean*** and/or the Diluent Syringe Cleaning Procedure described in **Section 9: *Service and Maintenance*, Subsection: *Nonscheduled Maintenance Procedures*, *Diluent Syringe Cleaning*.**
Insufficient or no dilution mixing.	Remove the Upper Front Cover. Press the Touch Plate. Observe the bubble mix in each bath. Obtain technical assistance as required.

Run cycle will not stop.

Probable Cause(s)	Corrective Action
Start Switch is stuck.	Turn the instrument Power Switch OFF. Remove the front covers and check the White Start Switch. For the 1700CS, also open the Closed Sample Assembly Door and check the White Start Switch.

Specimen will not aspirate.

Probable Cause(s)	Corrective Action
Fibrin or debris is in the Sample Aspiration Probe.	Check the specimen for fibrin clots or red blood cell agglutination. Redraw the specimen as required. Check the probe for fibrin clots, salt deposits, etc. Clean the interior part of the probe as described in **Section 9: *Service and Maintenance,* Subsection: *Nonscheduled Maintenance Procedures, Sample Aspiration Probe Interior Cleaning,*** or replace it if necessary as described in **Section 9: *Service and Maintenance,* Subsection: *Nonscheduled Maintenance Procedures, Aspiration Probe Removal and Replacement.***
Sample Syringe.	Ensure that the Sample Syringe is moving all the way up and down. Clean the Sample Syringe.
Vacuum or circuitry malfunction.	Obtain technical assistance.

STANDBY.

Probable Cause(s)	Corrective Action
No run cycle was activated for four hours. The Auto Shutdown cycle was activated, placing the unit in STANDBY.	Press **[PRIME/RUN]** to Prime the unit, and perform a background check.

The message WASTE FULL is displayed.

Probable Cause(s)	Corrective Action
Liquid level in the waste container has tripped the sensors.	Remove the Waste Stopper Assembly and empty the container. Press **[CLEAR ALARM]** to continue. Make sure the liquid is wiped from the stopper and the top of the bottle to ensure a good seal. **WARNING: Potential Biohazard.** Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.
Waste Sensor Plug is not inserted completely in the lower Left Side Panel receptacle. An audible tone sounds to alert the operator.	Reinsert the plug into the receptacle, then press **[CLEAR ALARM]** to continue.
Defective component.	Obtain technical assistance.

Waste full, no message displayed.

Probable Cause(s)	Corrective Action
Waste Sensor Plug on the lower Left Side Panel is dirty.	Clean the plug with alcohol and reinsert it fully.
Loose wire in the Waste Stopper Assembly.	Obtain technical assistance.

WBC and/or HGB data are invalid.

Probable Cause(s)	Corrective Action
No lyse reagent added. Malfunction of the Lyse Syringe.	Go to the **SPECIAL PROTOCOLS** menu and press **[LYSE PRIME]**. Confirm that lyse dispenses into the von Behrens WBC Transducer in the Prime cycle. As required, clean the Lyse Syringe as described in **Section 9: *Service and Maintenance,* Subsection: *Nonscheduled Maintenance Procedures, Lyse Syringe Cleaning/Replacement*** or obtain technical assistance.

X-B data are out for MCH and/or MCHC.

Probable Cause(s)	Corrective Action
Dirty HGB Flow Cell.	Perform the Hemoglobin Flow Cell Manual Cleaning Procedure as described in **Section 9:** ***Service and Maintenance,*** **Subsection:** ***Nonscheduled Maintenance Procedures, HGB Flow Cell Manual Cleaning.***
Amount or timing of lyse addition not optimal.	Check the Lyse Inlet Tubing for cracks and leaks. Perform the Lyse Inlet Tubing Rinse Procedure and Lyse Syringe Cleaning Procedure as described in **Section 9:** ***Service and Maintenance,*** **Subsection:** ***Monthly Maintenance Procedures, Lyse Inlet Tubing Rinse*** and **Subsection:** ***Nonscheduled Maintenance Procedures, Lyse Syringe Cleaning/Replacement.*** Obtain technical assistance as required.

X-B data are out for MCV.

Probable Cause(s)	Corrective Action
Dirty aperture.	Clean the aperture plate as described in **Section 9:** ***Service and Maintenance,*** **Subsection:** ***Nonscheduled Maintenance Procedures, Aperture Plates Cleaning.*** Obtain technical assistance as required.
Osmolarity change in diluent.	Try a new lot of diluent.

NOTES

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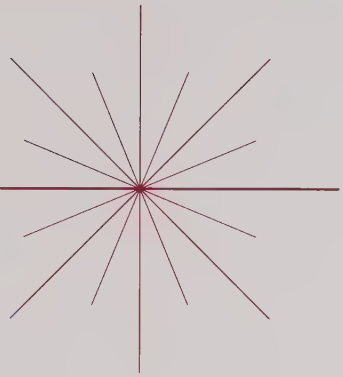
CELL-DYN® 1700 SYSTEM



Quality Control

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Quality Control

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Overview

The CELL-DYN® 1700 System offers several Quality Control (QC) options to monitor and validate instrument performance. The options are:

X-B Analysis — This QC option is useful for troubleshooting and confirming the calibration of the red blood cell parameters.

Commercial Controls — Numeric data obtained for each parameter is automatically transmitted to a designated file (Low Control, Normal Control, or High Control) when that control file is selected.

Replicate Specimen — This option works the same as the Commercial Controls program. The Replicate Specimen QC Program is nonspecific for specimen type. Therefore, it can be used for previously run specimens, precision specimens, etc.

Quality Control procedures, both internal and external, allow the operator to verify the performance of an analytical system. The use of Quality Control procedures in evaluating both commercial controls and patient samples facilitates the interpretation of laboratory data to ascertain acceptability of patient results.

The information in this section conforms to Abbott Laboratories' recommended procedures for Quality Control for all Abbott hematology instruments. It is recommended that these guidelines be incorporated into the procedure manual for your laboratory. In addition, refer to your laboratory's Standard Operating Procedures and/or Quality Assurance plan for additional Quality Control requirements.

This section contains the following subsections:

- Quality Control Guide
- Quality Control Menu
- X-B Analysis Program
- CELL-DYN 1700 Westgard Rules
- CELL-DYN Controls

NOTES

Quality Control Guide

Controls are used to determine whether an instrument is operating with accuracy and precision. Controls normally consist of fixed blood cells with assayed ranges for each measured parameter. Alternately, laboratories may use patient samples that were previously found to be within set patient limits. CELL-DYN Controls provide three control levels — low, normal, and high ranges — for each measured parameter.

Guidelines for Running Controls

Run a minimum of two levels of control at the beginning of each eight hours of operation prior to running patient samples. In addition, run controls after the following events:

- Change in reagent lot number
- Calibration
- Service call or component replacement
- Change in software version
- Selected maintenance procedures
- Special protocol
- Unusual trend or shift in patient results

In addition, follow your laboratory's protocol for Quality Control.

Mixing and Handling

Always mix and handle commercial control materials according to the directions given in the package insert. Because directions may vary from manufacturer to manufacturer, pay particular attention to the following:

- Check the condition of incoming control material. Be sure the vials are at the proper temperature and are not leaking. Check for hemolysis.
- Store controls at recommended temperatures inside the refrigerator, preferably in a central location away from the door.
- Carefully warm and resuspend the product according to the directions given in the package insert. Proper mixing is essential for accurate results.

- Check the shelf life and open-vial stability dating. Do not use products longer than recommended by the manufacturer or the results may be compromised.
- Never subject any vial to excessive heat or agitation.

Assay Verification

New lots of control material should be analyzed in parallel with current lots prior to their expiration dates. Perform the following steps to accomplish the transition to a new lot:

1. Set up a control file for the new lot.
2. Verify values for each new control lot by running each level of control in triplicate along with either replicate QC specimens or the old control when it is still in date.
3. Run the new controls twice a day for five days to establish a mean.
4. Use the mean of the ten runs to verify that the new lot yields the expected results. The mean should fall within the range specified by the manufacturer in the package insert.
5. If the calculated mean falls within the range specified by the manufacturer, use it in place of the manufacturer's stated mean.
6. When results for any parameter(s) are flagged (outside of operator-defined limits or reportable range), reconfirm calibration for that parameter using specimens with known reference values. When calibration confirmation results are acceptable, either establish a new working mean and limits for each level of the new lot of control or call the Abbott Customer Support Center.

A control file should be set up for the new lot number to easily establish the mean. If desired, this sample control file can then be used to run the control for the remainder of the dating period. It is not necessary to create another file.

The expected ranges published by manufacturers are generally too broad for effective Quality Control. Therefore, each laboratory should establish acceptable ranges. These ranges may be determined by evaluating three to six months of data (data from the Interlaboratory QC Program may be used) for a particular level of control. The individual SD (standard deviation) values may be averaged as follows:

$$\text{Average SD} = \sqrt{\frac{(N_1 \times SD_1^2) + (N_2 \times SD_2^2) + \ldots + (N_i \times SD_i^2)}{(N_1 + N_2 + \ldots + N_i) - i}}$$

N = number of values obtained in a month
SD = standard deviation of values obtained in that month
i = total number of months

The resulting long-term instrument SD and the laboratory-established mean for each lot number should be used to monitor instrument performance.

Running Controls

Abbott recommends using the CELL-DYN Control Materials for performing Quality Control checks on the CELL-DYN 1700 System. These controls should be run:

- After calibration (confirmatory step).
- After Daily Start-Up procedures are completed.
- After a reagent lot number change.
- After maintenance, a service call, or component replacement.
- In accordance with the laboratory's Quality Control protocol.
- According to regulatory requirements.

Controls should be run in the primary operating mode. Always do the following:

- If the system has been idle for fifteen minutes or more, a Normal Background should be run immediately prior to running any control specimens.
- Follow the proper warming and mixing procedures previously described, including those located on the control package insert.
- Run control samples for each measured parameter in the same manner as patient samples.

- Verify that control results are within the laboratory's acceptable limits.
- If the control results fall within acceptable limits, review the data for shifts or trends, record the results, and begin to process patient samples.
- If one or more result falls outside the laboratory's acceptable limits, review **Section 10**: ***Troubleshooting and Diagnostics,*** **Subsection:** ***Troubleshooting Guide*** and **Section 2**: ***Installation Procedures and Special Requirements,*** **Subsection:** ***Setup Instructions, QC Setup Key.*** Try using another vial from the same lot. If the problem persists, contact the Abbott Customer Support Center.

Quality Control Menu

Overview

This subsection discusses the options available when [QUALITY CONTROL] is pressed at the MAIN MENU.

The options used to set up the QC files are available by pressing [SETUP] in the MAIN MENU. The SETUP menu is used to activate or deactivate the Westgard Rules and to enter comparison data. Printed package insert reference mean and limits, the lot number, and the expiration date for control specimen in each file are also entered in the SETUP menu. Parameter results for any control run that fall outside of these entered limits are displayed in inverse video and underlined on the graphics printout and printed with an asterisk (*) on the ticket printout to alert the operator.

For details regarding setting up the X-B Files, Control Files, and Replicate Files, refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions.***

Commercial Controls

There are four files for each level of control: Low, Normal, and High. Each file can store 120 runs.

QC file summary data or Levey-Jennings® plot data currently in each file can be displayed and printed. Each time a QC specimen is run, the mean, standard deviation, and coefficient of variation for each parameter are calculated and updated automatically in each file. The operator can, at any time, reject any run with flagged (outside entered limits) data from this calculation. Additionally, the operator can delete any run from a QC file, or purge the entire QC file.

Replicate Specimens

Nine separate files are available for this program. Each replicate file can store numeric data for each parameter for up to 120 runs. Each file can be displayed or printed at any time.

Alerts, calculations, and plots are the same as those stated above for the commercial control QC program.

Quality Control Menu

The Quality Control files contain specific specimen records that were selected for inclusion in a particular control or replicate file prior to running those specimens. The operator can establish 21 QC files with each file storing a maximum of 120 runs. The **QUALITY CONTROL** menu allows the operator to perform the following functions:

- Purge QC files
- Accept and reject specimens from QC files
- Delete specimens from QC files
- Display and print Levey-Jennings® graphs
- Write QC files to floppy disks

At the **MAIN MENU**, press **[QUALITY CONTROL]** to display the **QUALITY CONTROL** menu. A brief description of each key, displayed at the bottom of the **QUALITY CONTROL** menu, and its function is given below.

X-B File

[X-B FILE] is used to display and print data and graphs for the MCV, MCH, and MCHC parameters, including the date and time for each batch.

Low Control

[LOW CONTROL] is used to display the Low Control file names and the number of specimens in each file. It also displays detailed QC information, such as limits, standard deviation, and coefficient of variation for each parameter for each lot number when the **[VIEW QC LOG]** key is pressed.

Normal Control

[NORMAL CONTROL] is used to display the Normal Control file names and the number of specimens in each file. It also displays detailed QC information, such as limits, standard deviation, and coefficient of variation for each parameter for each lot number when the **[VIEW QC LOG]** key is pressed.

High Control

[HIGH CONTROL] is used to display the High Control file names and the number of specimens in each file. It also displays detailed QC information, such as limits, standard deviation, and coefficient of variation for each parameter for each lot number when the **[VIEW QC LOG]** key is pressed.

Replicates

[REPLICATES] is used to display the replicated file names and number of specimens in each file. It also displays detailed QC information, such as limits, standard deviation, and coefficient of variation for each parameter for each replicate ID/lot number when the [VIEW QC LOG] key is pressed.

Using Quality Control

In the QUALITY CONTROL menu, press [LOW CONTROL], [NORMAL CONTROL], [HIGH CONTROL], or [REPLICATES] to access the appropriate screen. Use the arrow keys to select one of the four control files or one of the nine replicate files.

Each screen display (page) may contain up to 10 specimens. To view the previous page, use the Page Up key. To view the next page, use the Page Down key. Use the ← arrow and the → arrow keys to scroll through the complete list of parameters for all specimens displayed on a page.

View QC Log

With a file highlighted, press [VIEW QC LOG] to view a list of the specimens in that file by sequence number. The operator has the following options:

- Purge the QC log
- Display and print Levey-Jennings® graphs for the QC file
- Accept, reject, or delete the specimen indicated by the flashing cursor
- Print the QC log

The functions available when a control file or replicate file is selected are described below.

Levey-Jennings®

[LEVEY-JENNINGS] is used to display the LEVEY-JENNINGS menu.

Reject/Accept Specimen

[REJECT SPECIMEN] is used to reject the specimen indicated by the flashing cursor and places an "R" after the <Sequence #> field. Specimen results are not included in the calculation of N, mean, standard deviation, or coefficient of variation. When pressed, [REJECT SPECIMEN] changes to [ACCEPT SPECIMEN]. Press [ACCEPT SPECIMEN] to include the specimen in the statistical calculation and to remove the "R" next to the <Sequence #> field.

Purge QC Log

[PURGE QC LOG] is used to permanently erase data from the control file. After [PURGE QC LOG] is pressed, the screen label changes to [CONFIRM PURGE]. Press [CONFIRM PURGE] to complete the purge. Press [CANCEL PURGE] to cancel the purge.

> NOTE: Once [CONFIRM PURGE] is pressed, data in the file is permanently erased.

Write QC to Disk

The feature enabling the transfer of QC limits and data into a QC file from a floppy disk is not currently available. Therefore the following keys mentioned in this manual should not be used at this time: [Lab ID Setup] and [Write QC to Disk].

Delete Specimen

[DELETE SPECIMEN] is used to delete a specimen indicated by the flashing cursor from the control file. When [DELETE SPECIMEN] is pressed, only two keys are displayed: [CONFIRM DELETE] to complete the deletion and [CANCEL DELETE] to cancel the deletion. Deleted specimens are not included in statistical calculations.

Print QC Log

[PRINT QC LOG] is used to print the displayed QC file on the Graphics Printer.

X-B Analysis Program

Overview

X-B Analysis is an automated means of monitoring instrument performance by using the known stability of the red blood cell indices.

X-B represents the moving average of hematology values calculated using an algorithm developed by Dr. Brian Bull. The X-B Analysis uses the Bull Algorithm to monitor instrument performance by tracking the average red blood cell indices in the patient population analyzed on the instrument.

The red blood cell indices, MCV, MCH, and MCHC, are known to be stable because the red blood cell apparently functions best in a very narrow range of size and hemoglobin content. Therefore, the body exerts tight physiologic control and varies the number of red blood cells before altering the average volume or hemoglobin concentration of those red blood cells. Consequently, the average red blood cell indices of a given patient population will vary no more than 0.5% from day to day and even year to year, providing the population does not change. The X-B algorithm provides a means of utilizing this information for quality control on the CELL-DYN 1700.

The X-B algorithm analyzes the indices for MCV, MCH, and MCHC on the patient samples run through the instrument in batches of 20. Current batch data are then "smoothed" by using the mean from the previous batch in the calculation. As a result, each newly calculated batch mean includes data from previous batches.

When the X-B Program is ON and Patient is the specimen type selected, the current status of the X-B Program is displayed on the third line in the upper right corner of the **RUN** screen (for example, **X-B: N/IN**, where N is the number of runs in the current batch and IN indicates the last batch was within the target and limits for all three parameters). In the **DATA LOG** menu, a "B" in front of a sequence number indicates that the patient specimen *is* included in the current X-B batch.

Lower/Upper Acceptance Limits

The Lower and Upper Limits determine which patient results will be used in the X-B moving average calculation. They should be set wide to exclude grossly abnormal samples or background counts but should include at least 95% of the patient results. That way only results that fall within the set limits will be used in the calculation.

Target Value

The Target Value for X-B is similar to the assay value for a commercial control. It is derived from the patient population analyzed on the instrument.

Action Limit

The Action Limit is the acceptable limit of variation around the Target Value.

Establishing the Target Value

A 1992 study[1] by Dr. Bull collected data from 1,767 hospitals and yielded the following mean values:

- MCV 90.0 fL
- MCH 30.5 pg
- MCHC 33.9 g/dL

These values confirmed values that Bull published in an earlier study.[2] Consequently, the values shown above can be used as the Target Values to initiate the X-B Program.

To establish X-B Target Values in the **SETUP** menu for MCV, MCH, and MCHC:

1. In the **SETUP** menu, use the Enter key to turn the X-B Moving Average Program ON.
2. Press **[QC SETUP]** followed by **[X-B SETUP]**. Use the arrow keys to move the cursor to the Target Value column and enter the following:
   - "90." for MCV
   - "30.5" for MCH
   - "33.9" for MCHC

Laboratories such as pediatric hospitals and tumor centers with specialized patient populations may need to verify these Target Values due to "abnormal" patient populations. Target values may be verified by evaluating approximately 500 samples and comparing the X-B means for those samples to the entered Target Values. This can be done as follows:

1. Collect data from at least 500 patients. Manually calculate the mean, SD, and CV for each index (MCV, MCH, and MCHC). The CV on 500 samples for each index should be less than 1.5%. (The 1.5% is one-half the allowable ± 3% action limit.) If the CVs are greater than 1.5%, an additional 500 samples should be evaluated.
2. If the CVs calculated in step 1 are less than 1.5%, enter the mean as the Confirmed Target Value.

Interpreting X-B Results

A suggested protocol and guidelines for interpreting X-B data can be found in Section 1 of *Laboratory Hematology, An Account of Laboratory Techniques,* edited by I. Chanarin.[4]

NOTES

CELL-DYN 1700 Westgard Rules

The Westgard Rules may be used singly or in combination depending on the operator preference. Selections are made on the QC FILE SETUP menu. To select a specific control file, refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions, SETUP Screen Options, QC Setup Key.***

The number of the rule is displayed if that rule was violated. A plus (+) sign means the rule is turned ON, a minus (-) sign means the rule is turned OFF.

The modified Westgard Rules available on the CELL-DYN 1700 System are:

Rule 1: Value outside 3 SD:
A control result exceeded the mean ± 3 SD.

Rule 2: Two consecutive values outside the same 2 SD:
Two consecutive results fell outside 2 SD on the same side of the mean.

Rule 3: Two consecutive values outside opposite 2 SD:
One result was greater than 2 SD above the mean and the next result was greater than 2 SD below the mean; consequently, the range between the results is greater than 4 SD.

Rule 4: Two of three consecutive values outside the same 2 SD:
Two of three consecutive results fell outside 2 SD on the same side of the mean.

Rule 5: Four consecutive values outside the same 2 SD:
Four consecutive results fell outside 2 SD on the same side of the mean.

Rule 6: Twelve consecutive values on the same side of the mean:
Twelve consecutive results fell on the same side of the mean.

Rule Violations

Only the directly measured parameters need to be monitored with multiple rules. The following procedure is a synopsis of the protocol suggested by Cembrowski.[3]

Since three levels of control are typically used to monitor a hematology analyzer, it is reasonable to consider all three runs at the same time. In other words, check for rule violations across the three levels, not just within a particular level. If the same rule is violated at more than one level, determine whether the violation indicates a loss of precision or a loss of accuracy, and troubleshoot accordingly.

Cembrowski suggests that the results for all three levels first be checked to see if they are within their 2 SD limits. If all three levels meet this criterion, the instrument is in control.

If any control result exceeds the 2 SD limits, check to see if it exceeds the 3 SD limits. If a result exceeds 3 SD, there is either an instrument problem or a problem with the particular level of control. Therefore, if a result exceeds 3 SD, run another vial of that control. If the problem persists, then additional investigation is required.

Check to see if either Rule 3 or Rule 4 has been violated for any level or across levels. If the problem is confined to one level of control, check for a Rule 2 violation for that level. Again, if the violation is confined to one level of control, use another vial and, if possible, another lot. Check expiration dates and data entry. Check to be sure that the control is run into the correct file.

If a combination of rules has been violated across the three levels, determine whether the violations indicate a loss of precision or a loss of accuracy, and troubleshoot accordingly. If necessary, call the Abbott Customer Support Center for assistance.

When the problem has been resolved, Cembrowski suggests that all levels be run again in duplicate to confirm that the problem has, in fact, been corrected.

CELL-DYN Controls

The CELL-DYN controls are packaged as follows:

- Tri-level, 1 box, 2.5-mL vials x 12
- Tri-level, 1 box, 3.0-mL tubes x 12

NOTES

References

1. Bull BS, Richardson-Jones A, Gibson M, Twedt D. A Method for the Independent Assessment of the Accuracy of Hematology Whole Blood Calibrators. *American Journal of Clinical Pathology* 1992; 98:623-29.

2. Bull BS, Hay KL. Are Red Blood Cell Indexes International? *Archives of Pathology and Laboratory Medicine* 1985; 109:604-06.

3. Cembrowski GS, Westgard JO. Quality Control of Multichannel Hematology Analyzers: Evaluation of Bull's Algorithm. *American Journal of Clinical Pathology* 1985; 83:337-34.

4. Chanarin I. Laboratory Hematology: An Account of Laboratory Techniques. New York: Churchill Livingstone. 1989.

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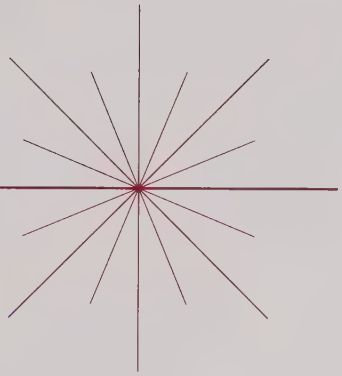

Printers

Printers

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NOTES

Overview

The CELL-DYN® 1700 System is configured for graphics printing to print graphics reports and ticket printing to print tickets. The printers can be identical; only the output will differ depending on the type of printout selected.

The graphics printing setup is used to print reports, including complete graphics information, on continuous tractor-feed paper. The ticket printing setup is used to print preprinted tickets on a printer identical to or similar to the Graphics Printer. This section gives a brief overview of the maintenance and troubleshooting procedures for both graphics and ticket printing.

NOTES

Graphics Printer

To print graphics, the printer cable must be connected to the Graphics Printer Port on the right side of the instrument. (For the location of these connectors, refer to Figure 1.6, Right Side Panel.) Instructions for installing the printer are given in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Printer Installation***. Complete directions for customizing the printout type and format are given in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions.*** For a detailed description of the printer components and for instructions on changing the ribbon and loading paper, refer to the manuals that accompany the printer.

The CELL-DYN 1700 System software automatically controls and adjusts most print conditions. Occasionally, a few settings may need to be changed in the printer software for correct operation. If printing is not what you expect, refer to the printer manual for guidance in making adjustments. If you have additional questions or experience any problems, call the Abbott Customer Support Center for assistance.

Troubleshooting

Refer to the printer manuals for a list of the most common printer problems and how to solve them. If the problem is not resolved, contact the Abbott Customer Support Center for assistance.

> **NOTE:** If, during routine system operation, the message **Printer NOT READY** is displayed, check to see if the printer cable is securely connected to the Data Module, if the Printer Power Switch is turned ON, and if the **[SEL]** (Select) indicator is illuminated. Press **[PRINT REPORT]**. If the message is still displayed, turn the Printer Power OFF, wait about five seconds, turn the power ON again, and press **[PRINT REPORT]**. If the message is still displayed, there may be an internal printer error. Contact the Abbott Customer Support Center for assistance.
>
> **NOTE:** The **[PRINT REPORT]** key varies slightly in the **QUALITY CONTROL** and **DATA LOG** menus.

NOTES

Ticket Printer

If ticket printing is desired for the CELL-DYN 1700 System, a second printer (known as the Ticket Printer) can also be connected to the system. Instructions for installing a second printer are given in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Installation, Printer Installation***. Complete directions for customizing the printout type and format are given in **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions.***

For detailed information about loading paper and changing the ribbon in the Ticket Printer, refer to the manuals that accompany the printer. In particular, note the important safety instructions.

Printing Tickets

To print tickets, the printer cable must be connected to the Ticket Printer Port on the right side of the instrument. For the location of these connectors, refer to Figure 1.6, Right Side Panel. For instructions for customizing either type of printout, refer to **Section 2: *Installation Procedures and Special Requirements,* Subsection: *Setup Instructions, SETUP Menu Screen*.**

Troubleshooting

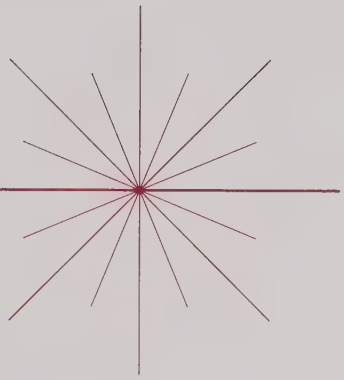
Refer to the printer manuals for a list of the most common printer problems and how to solve them. If the problem is not resolved, contact the Abbott Customer Support Center for assistance.

> NOTE: If, during routine system operation, the message **Printer NOT Ready** is displayed, check to see if the printer cable is securely connected to the Data Module, if the Printer Power Switch is turned ON, and if the **[SEL]** (Select) indicator is illuminated. Press **[PRINT REPORT]**. If the message is still displayed, turn the Printer Power OFF, wait about 5 seconds, turn the power ON again, and press **[PRINT TICKET]**. If the message is still displayed, there may be an internal printer error. Contact the Abbott Customer Support Center for assistance.

NOTES

ABBOTT

CELL-DYN® 1700 SYSTEM



CELL-DYN 1700CS
Closed Sample Aspiration

9340439A

CELL-DYN 1700CS — Closed Sample Aspiration

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Overview

The CELL-DYN® 1700CS System accepts specimens in Open, Pre-Dilute, and Closed Modes. For the Open and Pre-Dilute Modes, setup procedures and options, sample analysis, operating procedures, calibration, and troubleshooting for the CELL-DYN 1700CS System are similar to the CELL-DYN 1700 System. Installation, operating procedures, and calibration for the Closed Mode are discussed in this section.

The remainder of this section is divided into eleven major subsections:

- System Components
- Installation
- Sample Analysis Cycle
- Operational Specifications
- Performance Specifications
- Performance Characteristics
- Operating Instructions
- Calibration
- Hazards
- Service and Maintenance
- Quality Control

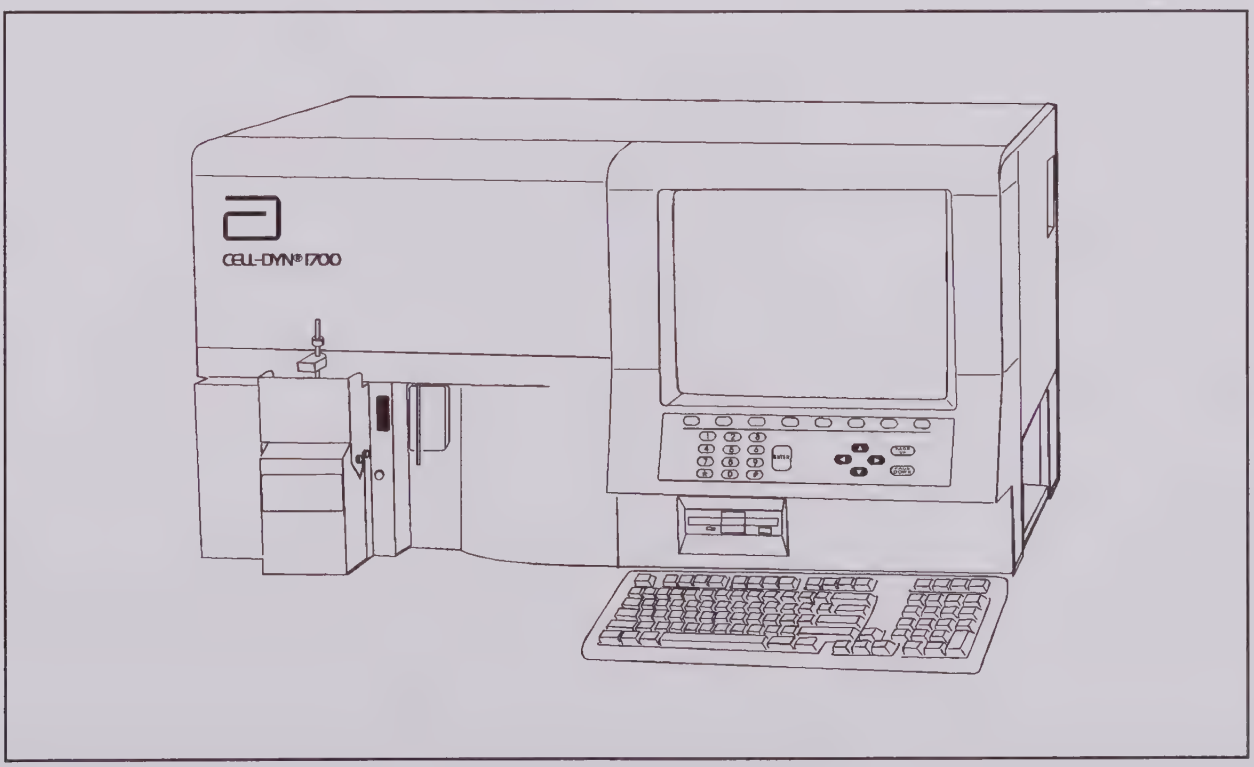

Figure 13.1: The CELL-DYN® 1700CS System

NOTES

System Components

The System components for the CELL-DYN 1700CS System are similar to the components in the CELL-DYN 1700 System. Refer to ***Section 1: Use or Function*** for a list and description of the major components. The one exception is the Closed Sample Assembly, which is described below.

Closed Sample Assembly

The CELL-DYN 1700CS System is equipped with an attached Closed Sample Aspiration Assembly, referred to as the Closed Sample Assembly. The assembly aspirates blood from a closed collection tube that has been inserted in the Sample Holder Well of the assembly.

The Closed Sample Assembly is mounted on a door that is hinged at the lower left front section of the Analyzer. When closed, the door is attached to the Analyzer by a Thumb Screw on the right side of the Closed Sample Assembly. Refer to the following figure.

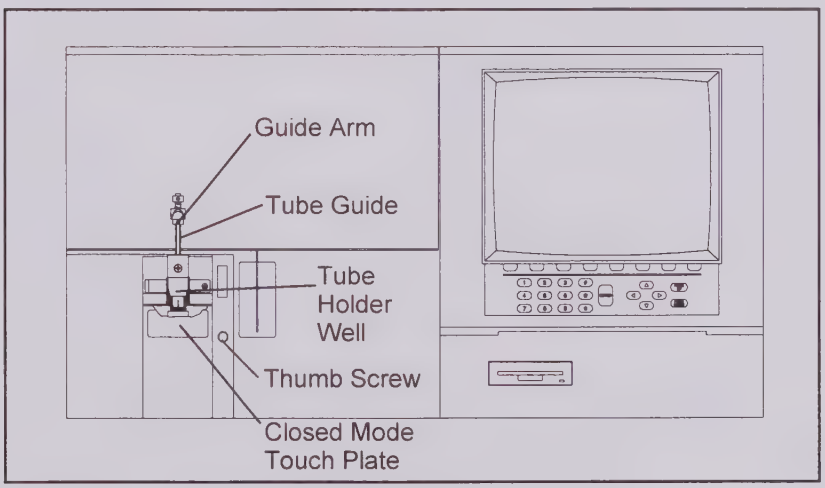

Figure 13.2: Closed Sample Assembly — Exterior

The assembly consists of the following components:

- Touch Plate
- Tube Holder Well
- Tube Guide
- Interlock Door
- Piercing Needle
- Sample Cup
- Two Peristaltic Pumps

The Flow Panel for the Closed Sample Assembly is located inside the assembly door. Refer to the following figure. To access the Flow Panel, turn the Thumb Screw counterclockwise until the door swings open.

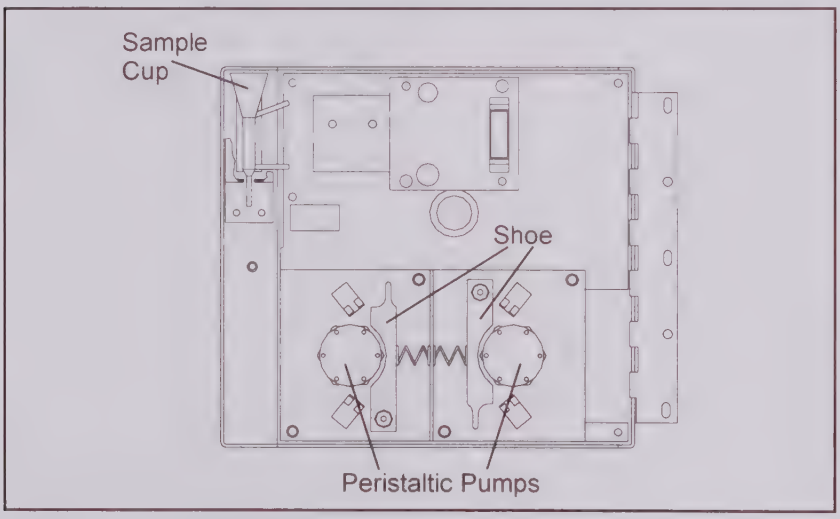

Figure 13.3: Closed Sample Assembly — Interior

Installation

The CELL-DYN 1700CS System instrument must be operational before the Closed Sample Assembly can function properly. The system is installed in the same manner as the CELL-DYN 1700 System. Refer to **Section 2: *Installation Procedures and Special Requirements,*** for installation instructions. One additional installation requirement is to install the tubing in both Peristaltic Pumps. For each pump, hook the square connectors at each end of the tubing onto the metal Holder Brackets to securely hold the tubing, then pull the Pump Shoe back and carefully insert the tubing between the pump and the Pump Shoe. Make sure the tubing is completely inserted. (Refer to ***Peristaltic Pump Tubing Removal/Replacement*** within this section.)

Flow Panel Inspection

To access the entire Flow Panel, both the Upper and Lower Front Covers must be removed. Removal of the covers on the CELL-DYN 1700CS differs slightly from the CELL-DYN 1700 because of the Closed Sample Assembly attached to the front of the Analyzer. Follow the directions below to remove the front covers from the Analyzer. Refer to Figure 13.2, Closed Sample Assembly — Exterior.

Upper Front Cover Removal

The Upper Front Cover must be removed to gain access to the Diluent Normally Closed Valve on the Flow Panel. The diluent tubing, normally inserted in this valve, was removed for shipment. To ensure correct system operation, this tubing must be completely inserted before the power is turned on.

1. Loosen the Thumb Screw on the Closed Sample Assembly by turning it counterclockwise until the door swings open. Swing the door open until the Tube Guide does not interfere with the removal of the Upper Front Cover.
2. Grasp the lower portion of the Upper Front Cover and pull it slightly upward (less than 1/4 inch) until it releases from the upper mount brackets, then pull the cover towards you.
3. To remove the cover completely, detach the ground wire at the connector attached to the left side of the instrument's main frame. Remove the cover and set it aside.

Lower Cover Removal

1. Locate the Thumb Screw, which holds the Lower Front Cover to the Analyzer frame, to the left of the Open Mode Touch Plate. Remove the screw by turning it counterclockwise and save it.
2. Slide the cover to your left about 1 inch until the right side is free of the screen Bezel Cover, then raise the cover about 1/2 inch to release the bottom edge from the lower mount brackets.
3. Pull the cover out and set it aside.

Reinstalling the Front Covers

1. Reinstall the Lower Front Cover and tighten the Thumb Screw.
2. Reinstall the Upper Front Cover. Remember to reattach the ground wire.

   NOTE: Performance may be affected if the ground wire is not reconnected before the cover is reinstalled.

3. Swing the Closed Sample Assembly door closed and tighten the Thumb Screw.

Tube Guide Adjustment

The Tube Guide in the Closed Sample Assembly is set at the factory to accept 75 mm high VACUTAINER® tubes. The Tube Guide Arm can be adjusted as necessary to accept 100 mm high VACUTAINER® tubes. Use the Allen wrench provided in the Accessory Kit to make any adjustment as follows:

1. Locate and remove the 3/32" Allen wrench provided in the Accessory Kit.
2. Turn the Tube Guide Arm to either side to gain access to the Lower Collar Nut Set Screw on the guide. Refer to the following figure.

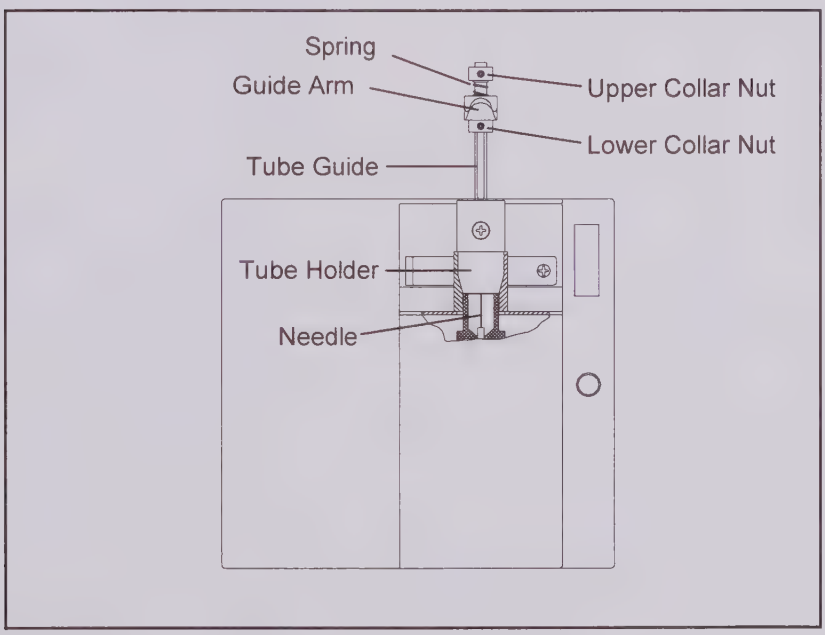

Figure 13.4: Sample Holder Well and Tube Guide

3. Insert the Allen wrench into the Lower Collar Nut Set Screw and turn the wrench counterclockwise to loosen the screw until the collar slides freely on the guide.
4. Insert the Allen wrench into the Upper Collar Nut and loosen the set screw until the collar slides freely on the guide.

   NOTE: Be careful not to slide the Guide Arm off of the Tube Guide. A small spring and ball bearing make it difficult to reinstall the arm back on the Tube Guide.

5. Turn the Tube Guide Arm to the center and insert the new VACUTAINER® tube into the Sample Well (cap facing down). Slide the Tube Guide Arm up or down until the tube is securely seated in the groove of the Guide Arm.
6. Carefully press down on the Upper Collar, pushing the spring down until the spring is almost completely compressed.
7. While holding down the Upper Collar, use the Allen wrench to tighten the collar nut.
8. Remove the VACUTAINER® tube, and turn the Tube Guide Arm to either side.
9. Move the Lower Collar up until it begins to push up the Guide Arm. Continue pushing the Guide Arm up until the spring is compressed approximately one-third, or until 1/4 inch of space remains between the Upper Collar and the top of the Guide Arm. While holding the Lower Collar in place, use the Allen wrench to tighten the Lower Collar Nut Set Screw.

   NOTE: The same type of VACUTAINER® tubes may vary slightly in length and thickness. There should be sufficient leeway in the spring to allow for these slight differences in length. (If the difference in length is greater than 1 mm, the Guide Arm should be readjusted). Too much leeway may result in the failure of the Piercing Needle to properly penetrate the cap and aspirate the sample. Too little leeway may make it difficult to snap the VACUTAINER® into place in the Guide Arm without having to readjust the collars. The operator may have to experiment to find the proper tension of the spring.

10. Turn the Tube Guide Arm back to center. Insert and remove the new size VACUTAINER® tube five to ten times to confirm that both collar nuts are tight and that the tube fits securely under the Guide Arm.

Sample Analysis Cycle

Closed Mode

To process samples in the Closed Sample Mode, perform the following sequence.

> **NOTE:** If the system has been idle for fifteen minutes or more, a Normal Background should be run in Open Mode, prior to running any specimens in the Closed Mode.

1. Invert a closed VACUTAINER® tube, place the tube in the Sample Holder Well with the cap facing down, carefully snap the tube in place, and close the Interlock Door.

⚠ **CAUTION:** The VACUTAINER® tube must contain at least 1.0 mL of blood.

2. Press the Touch Plate on the face of the Closed Sample Assembly to activate the cycle.

⚠ **CAUTION:** Repeated punctures of the VACUTAINER® tube's rubber stopper by the Piercing Needle may cause particles to break loose from the stopper and clog the needle opening. Do not aspirate more than six times using the same stopper. Either change the stopper or change the VACUTAINER® tube.

When the Closed Mode cycle is activated, the following events occur:

1. The needle in the bottom of the Sample Holder Well pierces the VACUTAINER® cap and a pump transfers 450 µL of blood into the Sample Cup in the assembly.
2. The Aspiration Probe then aspirates a 30-µL sample from the Sample Cup and dispenses this amount into the Pre-Mixing Cup located on the Flow Panel of the Analyzer.
3. The remaining procedures in the run cycle are the same for both versions of the instrument.
4. When the results are displayed on the screen, the message CLOSED is displayed in the upper right corner after the **<Sequence #>** field.

NOTES

Operational Specifications

Physical Dimensions

The physical dimensions of the CELL-DYN 1700CS are similar to those of the CELL-DYN 1700 except for an additional 2 inches of depth due to the Closed Sample Assembly. The physical dimensions of the instrument are listed in the following two tables.

Table 13.1: Physical Dimensions — CELL-DYN 1700CS

Dimension	Analyzer
Height	19" (49 cm)
Width	34" (87 cm)
Depth	26" (66 cm)
Weight	155 lbs (71 Kg)

Table 13.2: Physical Dimensions After Packaging for Shipment

Dimension	Analyzer
Height	30" (76 cm)
Width	42" (107 cm)
Depth	32" (81 cm)
Weight	210 lbs (96 kg)

Cycle Times (READY to READY)

The cycle times in the normal condition are equal to or less than:

Auto Start-Up:	240	seconds
Run (Closed Mode):	90	seconds *
Auto-Calibration:	90	seconds
Auto Shutdown:	300	seconds

* A run cycle in the Closed Mode with *no* Platelet Recount is equal to or less than 90 seconds; a run cycle in the Closed Mode *with* a Platelet Recount is equal to or less than 120 seconds.

NOTES

Performance Specifications

CELL-DYN 1700CS performance has been verified during evaluations performed on systems operated at Abbott Diagnostics and during evaluations performed with systems installed and operated in hematology laboratories at selected clinical sites.

> **NOTE:** Stated performance specifications apply only when the CELL-DYN 1700CS System is maintained and operated in accordance with the stated guidelines in this manual, using the specified diluent, lyse, and detergent reagents. Any system component change (e.g. recalibration, reagent brand or lot, etc.) during a period of time can affect the observed results.

Accuracy and Carryover

Accuracy and Carryover for the Closed Mode are shown in the following two tables.

Table 13.3: Whole Blood Accuracy Results — Closed Mode

Parameter	Range	Correlation Coefficient
WBC	0.5 – 96.5	≥ 0.98
LYM#	0.1 – 94.5	≥ 0.92
MID#	0.0 – 11.4	≥ 0.60
GRAN#	0.1 – 40.8	≥ 0.92
RBC	1.48 – 6.47	≥ 0.98
HGB	4.2 – 18.2	≥ 0.98
HCT	12.5 – 55.3	≥ 0.98
MCV	63 – 113	≥ 0.98
RDW	10.8 – 27.6	≥ 0.92
PLT	11 – 939	≥ 0.98
MPV	6.4 – 15.4	≥ 0.92

Table 13.4: Carryover — Closed Mode

	WBC (K/μL)	RBC (M/μL)	HGB (g/dL)	PLT (K/μL)
Level	90.0	6.20	22.0	900
% Carryover	< 1.0	< 0.5	< 0.8	< 1.0

Within Sample Precision

Hemogram Parameter

The following table presents the precision specifications for the hemogram parameters for specimens run on the CELL-DYN 1700CS System in Closed Mode. For a discussion of how these values were determined, refer to **Section 4: *Performance Characteristics and Specifications*, Subsection: *Performance Specifications, Precision.*** The stated CV% in this table represents the instrument precision at a 95% confidence level from N=20 replicate runs.

Table 13.5: Within Sample Precision of the Hemogram Parameters — Closed Mode

Parameter	CV%
WBC	≤ 2.7
RBC	≤ 1.7
HGB	≤ 1.2
MCV	≤ 1.5
PLT	≤ 6.0
MPV	≤ 6.0

WBC Differential Parameters

Precision specifications for the WBC Differential parameters are given as a 95% confidence limit for a range of values for each of the WBC subpopulations.

Table 13.6: Precision of the WBC Differential Parameters — Closed Mode

Cell Type	Range	95% Confidence Limit
Lymphocyte %	18 – 57%	±3.1%
Mid %	4 – 9%	±1.6%
Granulocyte %	36 – 77%	±3.5%

Mode to Mode Bias

The CELL-DYN 1700CS System can be calibrated to agree with reference values within the allowable calibration ranges. All three modes of operation, Open, Pre-Dilute, and Closed, may be calibrated. Thus, it is possible to compensate for any differences which may exist between operation modes due to differing aspiration pathways or operational sequences. When each mode is properly calibrated according to the directions provided in this manual, bias between modes is clinically insignificant.

Performance Characteristics

Typical Precision

Performance characteristics provide a concise summary of system performance when operated under normal laboratory conditions. The pooled precision values (CV%) for the Hemogram Parameters Within Sample, shown in the following table, are based on the analysis of data from replicate runs of N=20.

Table 13.7: Typical Within Sample Precision Results — Closed Mode

Parameter	Typical Precision Within Sample	
	Range	CV%
WBC (K/µL)	4.0 – 11.4	2.2
RBC (M/µL)	3.92 – 5.47	1.4
HGB (g/dL)	11.7 – 16.7	1.0
MCV (fL)	73 – 100	1.0
PLT (K/µL)	165 – 408	3.2
MPV (fL)	7.3 – 12.4	4.2

NOTES

Operating Instructions

Closed Mode

Perform the following steps to operate the instrument in the Closed Sample Mode.

> **NOTE:** If the system has been idle for fifteen minutes or more, a Normal Background should be run prior to running any specimens in the Closed Mode.

1. Pull the hinged Interlock Door on the front of the Closed Sample Assembly forward to expose the Sample Holder Well.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

2. Place an inverted (cap facing down) closed VACUTAINER® tube into the Sample Holder Well and carefully snap the tube into the Tube Guide to securely hold the tube.

CAUTION: The VACUTAINER® tube must contain at least 1.0 mL of blood.

3. Close the Interlock Door. This door is a safety measure; the Touch Plate will not activate the run cycle if the door is not securely closed.
4. Press the Touch Plate on the front of the Closed Sample Assembly to activate the run cycle.

The upper right corner of the **RUN** menu displays the following information:

- Current date and time
- Operator ID — identification of the current operator
- Sequence # — automatically incremented as samples are run
- Limit set (1 to 4, defaults to 1) only when Patient is the selected specimen type
- Sampling mode (Open/Closed)

Data Log

The letter C is displayed to the left of the **<Date>** field in the **DATA LOG** menu for each specimen run in the Closed Mode.

All other operating instructions and procedures in the Closed Sample Mode are similar to the CELL-DYN 1700 System Open Mode.

Calibration

Overview

The Calibration Procedures for the Open and Pre-Dilute Modes on the CELL-DYN 1700CS System are similar to the CELL-DYN 1700 System. Review **Section 6: *Calibration Procedures*** prior to calibrating the CELL-DYN 1700CS System.

Use only fresh whole blood to calibrate in the Closed Mode. Your CELL-DYN 1700CS — Open Mode may be used as the reference instrument to obtain Reference Mean Values. You must calibrate the Open Mode (using either calibrator or fresh whole blood) before calibrating the Closed Mode.

The CELL-DYN 1700CS System displays different messages on the Data Module screen, depending on whether Open Mode or Closed Mode has been selected, and the [OPEN FACTORS] key toggles between [CLOSED FACTORS] and [OPEN FACTORS].

Closed Mode Calibration Confirmation

Before proceeding to calibrate the Closed Mode, perform the following steps to determine if Closed Mode Calibration is necessary.

1. Confirm that the system has been properly calibrated in the Open Mode as described in **Section 6: *Calibration Procedures***.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures

2. Obtain a normal fresh whole blood sample. A full 5-mL tube is required. Select an empty replicate file and run the sample five times in the Open Mode and five times in the Closed Mode.

3. Observe the Coefficient of Variation (CV) values for each parameter and compare these values to the following:

WBC	≤ 2.7%
RBC	≤ 1.7%
HGB	≤ 1.2%
MCV	≤ 1.5%
PLT	≤ 6.0%

   For acceptable ranges, refer to Table 13.5, Within Sample Precision of the Hemogram Parameters — Closed Mode.

4. If all parameters are within these limits, document in your laboratory's instrument logbook that Closed Mode Calibration Confirmation was performed. There is no need to calibrate the Closed Mode.

   If one or more parameters do not meet these criteria, repeat steps 2 through 4 using a different fresh whole blood sample.

5. If the results from the second sample fail to meet the above criteria for any parameter, perform the Closed Mode Calibration Procedure described below.

Auto-Cal Procedure

The Auto-Cal Procedure in the Closed Mode is similar to calibrating in the Open Mode using fresh whole blood as described in **Section 6: *Calibration Procedures*, Subsection: *Open Mode Calibration, Auto-Cal Method, Auto-Cal Procedure — Fresh Whole Blood*.**

> **NOTE:** For specific requirements regarding the fresh whole blood samples used in the calibration process, refer to **Section 6: *Calibration Procedures*, Subsection: *Calibration Guidelines, Fresh Whole Blood Sample Requirements*** and **Section 6: *Calibration Procedures*, Subsection: *Open Mode Calibration, Auto-Cal Method, Auto-Cal Ranges for Calibrator and Fresh Whole Blood*.**

Determining Reference Values — Auto-Cal

Perform the following steps to obtain Reference Mean Values before calibrating the instrument in the Closed Sample Mode:

1. In the Open Mode **RUN** menu, press **[SPECIMEN TYPE]** followed by **[QC TYPE]** and **[REPLICATES]**.
2. Using the arrow keys, select an empty replicate file and press **[RETURN]** to return to the **RUN** menu. The replicate file selected is displayed in the upper left corner of the screen.

3. Obtain five different samples of fresh whole blood.
4. Mix sample #1 well by inverting it at least ten times. Do not shake the specimen. Run a minimum of three replicates in the Open Mode from sample #1.
5. Press **[MAIN]** to access the **MAIN MENU**. Press **[QUALITY CONTROL]** followed by **[REPLICATES]**. Using the arrow keys, select the replicate file that received the three specimens. Press **[VIEW QC LOG]** followed by **[PRINT QC LOG]** to obtain a printout of the results, which will include the Reference Mean Values of the three runs for all parameters. Be sure to label the means from Sample #1 as Means #1, etc.
6. Purge the replicate file by pressing **[PURGE QC LOG]** followed by **[CONFIRM PURGE]**.
7. Press **[RETURN]** followed by **[MAIN]** and **[RUN]**.
8. Repeat steps 4 through 7 for samples #2 through #5. Be sure the Reference Mean Values derived from each of the remaining samples are clearly identified with that sample's number, for example, #2, #3, etc.

Auto-Cal Calibration — Fresh Whole Blood

1. Use the same samples run in the Open Mode for Closed Mode Auto-Cal Calibration Reference Values. Make sure that each VACUTAINER® tube is securely capped.
2. In the **MAIN MENU**, press **[CALIBRATION]** to display the **CALIBRATION** menu. Press **[CLOSED FACTORS]** to display the Whole Blood Closed Sample Factors screen. Press **[PRINT]** to print the current Calibration Factors. Press **[AUTO-CAL SELECT]** to display the **AUTO CALIBRATION** menu.
3. Press **[WHOLE BLOOD]** to display the **WHOLE BLOOD CALIBRATION** menu.
4. Use the arrow keys to place the cursor on the first parameter to be calibrated. Use the Enter key to toggle between YES and NO to select the parameters for calibration. When YES is displayed next to the parameter, the cursor is positioned in the Value field for that parameter.
5. Select sample #1 that was run in the Open Mode. Using the Reference Mean Value derived from Open Mode, enter the corresponding Reference Mean Value for each parameter to be calibrated. As each value is entered, the field accepts the value and the cursor automatically moves to the next parameter. Use the arrow keys to skip a parameter.

NOTE: When entering a Reference Mean Value for MCV, the value field on the Calibration screen accepts only a two-digit number. Therefore, when entering an MCV Reference Mean Value from the replicate file mean, follow these instructions:

- A digit to be rounded is not changed if it is followed by a digit less than five.

  Example: 86.4 would be rounded to 86

- If the digit to be rounded is followed by a digit greater than five or by five followed by other nonzero digits, it is increased by one.

  Example: 86.6 would be rounded to 87
  86.54 would be rounded to 87

- When the digit to be rounded is followed by five it is unchanged if it is even but increased by one if it is odd.

  Example: 86.5 would be rounded to 86
  87.5 would be rounded to 88

- All values within the same calculation should be carried out to the same decimal place.

NOTE: When MCV is selected, the message **Reference value for MCV may be supplied by entering values for RBC and HCT. To do so, press # and enter values when prompted** appears in the lower screen. When the pound (#) key is pressed, MCV changes to RBC, allowing the operator to enter the Red Blood Cells Reference Value (using three digits). Then **<HCT>** appears, allowing the operator to enter the Hematocrit Reference Value. The computer-calculated MCV Reference Value must be within the normal range of 80 to 100 to be accepted and displayed.

6. Mix the sample well by inverting it at least ten times. Do not shake the specimen.

7. When READY appears on the screen, place the well mixed sample #1 VACUTAINER® tube into the Sample Holder Well, and carefully snap the tube into the Tube Guide to securely hold the tube. Close the Interlock Door. Press the Touch Plate on the front of the Closed Sample Assembly to activate the run cycle. The Analyzer performs RUN 1 and displays the values in the RUN 1 column. Remove the sample from the Sample Holder between each run and mix by inverting at least ten times. Repeat this step for RUN 2 and RUN 3 measurements. The whole blood method requires three "good" runs to automatically calculate the Factor and Mean Factor for those parameters selected for calibration.

NOTE: the Auto-Cal program automatically compares the results of the first run with the parameter Reference Mean Value entered for that sample to verify that the difference is within acceptable limits. If any of the runs fails this Reference Check, the results are highlighted and no calibration factor will be calculated for that parameter. See **Section 6: *Calibration Procedures, Calibration Troubleshooting.***

8. After three "good" runs, the Factor and Mean Factor for each parameter to be calibrated are calculated by the system.

   If after three runs the Factor and Mean Factor have not been calibrated, one of the following conditions may exist:

   > < is displayed in the Factor column and a Mean Factor will not be calculated and displayed, if the instrument fails the precision check. After three "good" runs, the instrument performs a precision check for each parameter being calibrated before determining the Factor and Mean Factor for that parameter. See **Section 6: *Calibration Procedures, Calibration Troubleshooting.***

   >>> or <<< is displayed in the Factor Column and a Mean Factor is not calculated if the instrument fails the Allowable Limits used for calculating the Mean Factor.

9. Repeat steps 4 through 8 four more times for the remaining four reference samples. Enter the new Reference Mean Values that correspond with each of the remaining four samples before running the specimens, enter the Reference Mean Value for sample #2, then run sample #2, etc. A new factor for each parameter to be calibrated will be calculated each time three runs are completed for a sample. The Mean Factor for each parameter will be based on the total number of runs. When all five samples have been run in triplicate (15 runs) the instrument is calibrated.

   ⚠ CAUTION: Repeated punctures of the VACUTAINER® tube's rubber stopper by the Piercing Needle may cause particles to break loose from the stopper and clog the needle opening. Do not aspirate more than six times using the same stopper. Either change the stopper or change the VACUTAINER® tube.

10. Press **[RETURN]** to save the Calibration Factors.
11. Press **[PRINT]** to print a copy of the New Calibration Factors.
12. Press **[RETURN]** to return to the **CALIBRATION** menu.
13. Press **[MAIN]** to return to the **MAIN MENU**.

14. Press [RUN] to display the RUN menu.
15. Run three levels of controls in Closed Mode and confirm that the results obtained for all parameters are within control limits specified on the assay sheet or within your own established laboratory ranges of the current lot number.

Enter Factor Procedure

Determining Reference Values — Fresh Whole Blood

Use the following procedure to determine the reference values that will be used in the Closed Mode Enter Factor Calibration Procedure. No more than two hours should elapse between determining the Reference Mean Values and performing the calibration.

1. In the Open Mode RUN menu, press [SPECIMEN TYPE] followed by [QC TYPE] and [REPLICATES].
2. Using the arrow keys, select an empty replicate file and press [RETURN] to return to the RUN menu. The replicate file selected is displayed in the upper left corner of the screen.
3. Obtain five different samples of fresh whole blood. Label the five samples #1 through #5.
4. Mix sample #1 well by inverting it at least ten times. Do not shake the specimen. Run a minimum of three replicates in the Open Mode from sample #1.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Use established, good laboratory working practices when handling specimens. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910. 1030) or other equivalent biosafety procedures

5. Repeat step 4 with samples #2 through #5.
6. Press [MAIN] to access the MAIN MENU. Press [QUALITY CONTROL] followed by [REPLICATES]. Using the arrow keys, select the same replicate file that received the 15 specimens. Press [VIEW QC LOG] followed by [PRINT QC LOG] to obtain a printout of the results, which will include the means of all 15 runs for all parameters.

Enter Factor Calibration — Fresh Whole Blood

1. Open an empty replicate file.
2. Mix sample #1 well by inverting it at least ten times. Do not shake the specimen.
3. When READY appears on the screen, place the well mixed sample #1 VACUTAINER® tube into the Sample Holder Well, and carefully snap the tube into the Tube Guide to securely hold the tube. Close the Interlock Door. Press the Touch Plate on the front of the Closed Sample Assembly to activate the run cycle. When the cycle is completed, remove the sample from the Sample Holder. Mix the sample by inverting at least ten times. Repeat this step for RUN 2 and RUN 3 measurements.

   The results of the runs are placed in the replicate file selected in step 1.
4. Repeat step 3 for each of the remaining four specimens for a total of 15 runs. Run all specimens in the same replicate file to obtain a CELL-DYN Closed Mode Mean for all parameters.
5. Press **[MAIN]**. Press **[QUALITY CONTROL]**, followed by **[REPLICATES]** and select the appropriate replicate file.
6. Press **[VIEW QC LOG]** and press **[PRINT QC LOG]** to print the Summary Report for the selected replicate file. Return to **MAIN MENU**. These are your Closed Mode CELL-DYN Means.
7. Press **[CALIBRATION]** and **[CLOSED FACTORS]** to display Whole Blood Closed Sample Factors. Press **[PRINT]** to obtain a copy of the Current Closed Mode Calibration Factors which will be used in determining the new calibration factors.

8. To determine the new calibration factor:

   Use the Reference Mean Values determined in ***Calibration, Enter Factor Procedure — Determining Reference Values — Fresh Whole Blood*** within this section, and the CELL-DYN Closed Mode Mean Values determined in steps 2 through 4. Enter this information in the Enter Factor Closed Sample Mode Whole Blood Calibration Worksheet provided at the end of this procedure to calculate the New Closed Mode Calibration Factor for each parameter as follows:

   Whole Blood Calibration:

   $$\frac{\text{Reference Mean}}{\text{Closed Mode Mean}} \times \text{Current Closed Mode Calibration Factor} = \text{New Closed Mode Calibration Factor}$$

   For example, if the Reference Mean for WBC is 6.6, the CELL-DYN Mean for WBC is 7.1, and the current Closed Mode Calibration Factor for WBC is 0.98, then:

   $$(6.6 / 7.1) \times 0.98 = 0.91$$

   and 0.91 is your New Closed Mode Calibration Factor.

9. With the **CALIBRATION** menu displayed, press **[ENTER FACTOR]**.

10. Use the arrow keys to select the first factor to be changed. Enter the three-digit New Calibration Factor calculated from step 7. The cursor automatically advances to the next factor. Use the arrow keys to select a parameter.

    NOTE: **[RESTORE FACTORS]** is used to recall factors, stored on the Hard Disk, corresponding to the current mode — Open, Closed, or Pre-Dilute. **[RESET ALL TO 1.00]** is used to reset all factors displayed on the screen to 1.00.

11. Press **[RETURN]** to save the Calibration Factors.

12. Press **[PRINT]** to print a copy of the New Calibration Factors.

13. Press **[MAIN]** to return to the **MAIN MENU**.

14. Confirm calibration of the CELL-DYN 1700 System by the following method:

    Run three levels of controls and confirm that the results obtained for all parameters are within the control limits specified on the assay sheet or within your own established laboratory ranges for the current lot number.

    NOTE: If the results for any parameter are consistently out, repeat calibration or obtain technical assistance by contacting the Abbott Customer Support Center.

Hazards

The hazards discussed for the CELL-DYN 1700CS are similar to the CELL-DYN 1700. Refer to **Section 8:** ***Hazards.***

WARNING: Potential Biohazard. In addition to the hazards discussed in **Section 8**, the Closed Sample Assembly contains a needle in the bottom of the Sample Holder Well. The needle is sharp and potentially contaminated with infectious materials (e.g., patient samples, reagents, and controls). Avoid any contact with the needle.

NOTES

Service and Maintenance

The service and maintenance procedures for the CELL-DYN 1700CS System are similar to the CELL-DYN 1700 System. Refer to **Section 9:** ***Service and Maintenance.***

In addition to the maintenance procedures discussed in **Section 9,** it is necessary to clean components in the Closed Sample Assembly. The procedure for Auto-Cleaning the Closed Sample Assembly and the Tube Holder Well are listed below.

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8:** ***Hazards*** for additional information.

Closed Sample Auto-Clean

Materials Required

1. CELL-DYN Enzymatic Cleaner. (Enzymatic Cleaner should be used at room temperature but stored at a temperature between 2 and 8°C, or between 36 and 46°F.)
2. Red-top VACUTAINER® tube (with no anticoagulant).
3. DYN-A-WIPE™ lint-free pad (or other lint-free pad).
4. Gloves.
5. Lab coat.
6. Safety glasses.

Frequency

Perform this cleaning procedure weekly.

Procedure

1. Fill the VACUTAINER® tube with Enzymatic Cleaner to 3/4 full.
2. Wipe the top of the VACUTAINER® tube with a DYN-A-WIPE™ lint-free pad or other lint-free pad to remove any excess cleaner, and insert the stopper.

CAUTION: Enzymatic Cleaner is extremely slippery and any cleaner on the stopper or the top of the VACUTAINER® tube can cause the stopper to come off.

3. At the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
4. Confirm that the stopper is securely inserted in the VACUTAINER® tube containing the cleaner. Invert the tube and insert it into the Sample Holder Well.
5. Press **[AUTO CLEAN]** followed by **[START CLEAN]**. The message **PROCESS ACTIVE** is displayed on the screen. The Closed Sample Auto-Clean procedure takes approximately eight minutes.
6. At the beep, remove the sample tube from the Sample Holder Well.
7. When the cleaning cycle is finished, press **[MAIN]** to return to the **MAIN MENU**.
8. Press the **[RUN]** key followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**. Press the Touch Plate to run a background count.
9. Continue to run background counts until acceptable results are obtained for all background parameters.
10. Record this maintenance in your maintenance log.

Tube Holder Well Cleaning

Materials Required

1. CELL-DYN Enzymatic Cleaner or filtered bleach or detergent reagent. (Enzymatic Cleaner should be used at room temperature but stored at a temperature between 2 and 8°C, or between 36 and 46°F.)
2. Lint-free swab.
3. DYN-A-WIPE™ lint-free pad (or other lint-free pad).
4. Gloves.
5. Lab coat.
6. Safety glasses.

Frequency

Perform this cleaning procedure daily when samples are run in the Closed Mode.

Procedure

The **[CLEAN SAMPLER]** key is used to clean only the Sample Holder Well.

> NOTE: The Closed Sample Holder can also be cleaned by using the **[AUTO CLEAN]** key. This procedure also aspirates liquid and spilled blood or cleaning fluid from inside the holder. A lint-free swab can also be used to clean the inside of the Tube Holder.

1. Swing the Tube Guide Arm to the side for better visibility of the well.
2. Insert the tip of the Enzymatic Cleaner or pour the detergent into the Tube Holder Well and fill it 3/4 full. Leave the solution in the well for three to five minutes so that the waste can be soaked out from the well.

WARNING: Potential Biohazard. The needle in the Sample Holder Well is sharp and potentially contaminated with infectious materials. Avoid any contact with the needle.

3. Use a swab to clean the lip inside the holder well and the inside part of the well. Use a DYN-A-WIPE™ lint-free pad or similar material to wipe the outside part of the well. When finished, dispose of the applicator and DYN-A-WIPE™ pad in a biohazard safety container.
4. At the **MAIN MENU**, press **[SPECIAL PROTOCOLS]**.
5. Press **[CLEAN SAMPLER]**. The message **PROCESS ACTIVE** is displayed on the screen. The Clean Sampler procedure takes approximately one minute.

   > NOTE: Look for two parallel streams of diluent that flush the inner well.

6. When the cleaning cycle is finished, press **[MAIN]** to return to the **MAIN MENU**.
7. Press the **[RUN]** key followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**. Press the Touch Plate to run a background count.
8. Continue to run background counts until acceptable results are obtained for all background parameters.
9. Record this maintenance in your maintenance log.

Peristaltic Pump Tubing Removal/Replacement

This procedure is to be used for removing and/or replacing the Peristaltic Pump Tubing as needed, based upon volume and usage at individual laboratories.

Materials Required

1. New Peristaltic Pump Tubing
2. Gloves
3. Lab coat
4. Safety glasses

Procedure

1. Open up the Closed Sample Assembly (see figure below) by unscrewing the Thumb Screw counterclockwise, and swing the door open

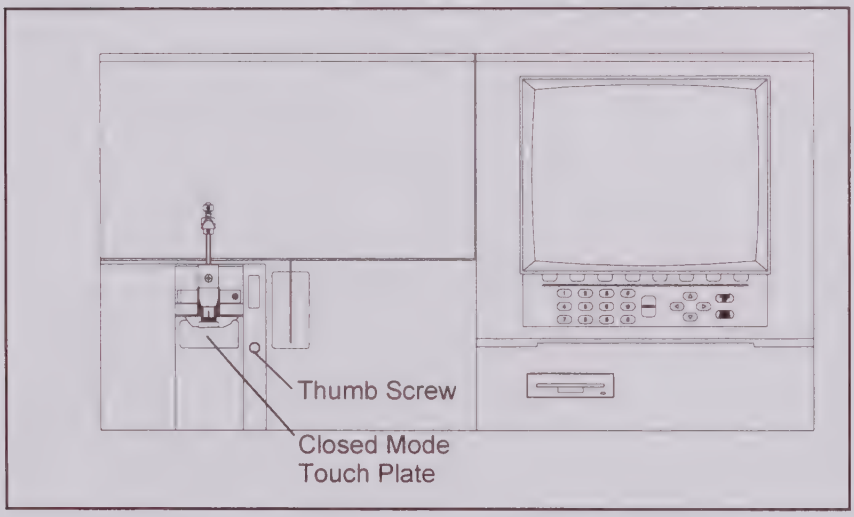

Figure 13.5: Closed Sample Assembly — Exterior

2. While referring to the figure below, locate the two Peristaltic Pump Wheels, the Pump Tubing Holder Brackets, and the Pump Shoes.

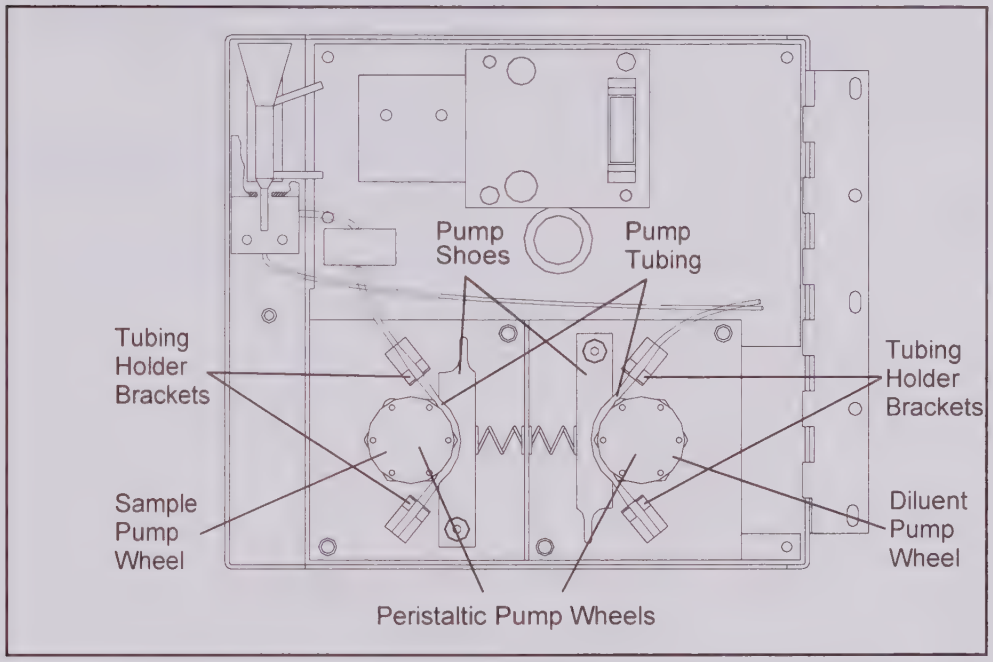

Figure 13.6: Closed Sample Assembly — Interior

3. To remove the pump tubing, grasp one end of the tubing and stretch the tubing sufficiently to pull it out from the Tubing Holder Bracket.
4. Push the Pump Shoe away from the pump tubing and carefully pull the tubing out from under the wheel.
5. Unhook the other end of the pump tubing from its bracket.
6. To replace the pump tubing, pull the tubing off of both end connectors. Push the replacement tubing back on these same two loose connectors.
7. To reinstall the Peristaltic Pump Tubing, reinsert both connector-fitting ends back in the Tubing Holder Brackets and push the tubing back underneath the Pump Wheel and Shoe.
8. Close the Closed Sample Assembly door and tighten the Thumb Screw fully clockwise.
9. Record this maintenance in your maintenance log.

Prolonged Shutdown

In addition to removing the tubing from the Normally Closed Valves as described in **Section 9: *Service and Maintenance,* Subsection: *Daily Maintenance Procedures, Prolonged Shutdown,*** remove the tubing in both Peristaltic Pumps as follows:

- Pull the Pump Shoe away from the pump and pull the tubing out. It is not necessary to remove the tubing from the two metal clips located above and below the pump.

Be sure to reinstall the Peristaltic Pump Tubing before turning the instrument back ON.

Quality Control

The Quality Control procedures and options for the CELL-DYN 1700CS System are similar to the CELL-DYN 1700 System. Refer to **Section 11:** ***Quality Control.***

> **NOTE:** The letter C is displayed to the left of the **<Date>** field in the **QC LOG** for each specimen run in the Closed Mode.

NOTES

Enter Factor Closed Sample Mode
Whole Blood Calibration Worksheet

Date: _____

Name: _____

Calculate all calibration factors to two decimal places.

New Closed Sample Calibration Factors

$$\frac{\textit{Open Mode Mean}}{\textit{Closed Mode Mean}} \times \textit{Current Closed Sample Calibration Factor} = \textit{New Closed Sample Calibration Factor}$$

	Open Mode Mean	÷	Closed Mode Mean	×	Closed Sample Calibration Factor	=	New Closed Sample Calibration Factor	Range*
WBC		÷		×		=		0.700 - 1.300
RBC		÷		×		=		0.800 - 1.200
HGB		÷		×		=		0.700 - 1.300
MCV		÷		×		=		0.700 - 1.300
PLT		÷		×		=		0.700 - 1.300

* If factor exceeds limits, **do not calibrate**. Check all calculations and call Abbott Customer Support Center for assistance.

NOTES

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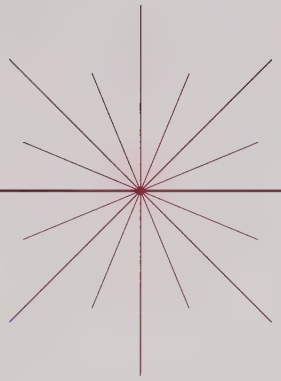
CELL-DYN® 1700 SYSTEM



Bibliography

Bibliography

Bessman J D. *Automated Blood Counts and Differentials.* Baltimore: Johns Hopkins University Press. 1986.

Barnett RN. *Clinical Laboratory Statistics*. Boston: Little, Brown and Company. 1979.

Brown BA. *Hematology: Principles and Procedures.* Philadelphia: Lea & Febiger. 1993.

Bull BS, Hay KL. Are Red Blood Cell Indexes International? *Archives of Pathology and Laboratory Medicine* 1985; 109:604-606.

Bull BS, Richardson-Jones A, Gibson M, Twedt D. A Method for the Independent Assessment of the Accuracy of Hematology Whole Blood Calibrators. *American Journal of Clinical Pathology* 1992; 98:623-29.

Campbell MJ and Machin D. *Medical Statistics: A Common Sense Approach.* New York: John Wiley & Son. 1993.

Cembrowski GS, Westgard JO. Quality Control of Multichannel Hematology Analyzers: Evaluation of Bull's Algorithm. *American Journal of Clinical Pathology* 1985; 83:337-34.

Chanarin I. Laboratory Hematology: *An account of Laboratory Techniques.* New York: Churchill Livingstone. 1989.

Cornbleet J. Spurious Results from Automated Hematology Cell Counters. *Laboratory Medicine* 1983; 14:509-514.

Hillman RS and Finch CA. *Red Cell Manual.* Philadelphia: FA Davis Company. 1992.

International Committee for Standardization in Hematology (ICSH). The Assignment of Values to Fresh Blood Used for Calibrating Automated Cell Counters. *Clinical and Laboratory Hematology* 1988; 10:203-212.

International Committee for Standardization in Hematology (ICSH). Protocol for Evaluation of Automated Blood Cell Counters. *Clinical and Laboratory Hematology.* 1988; 10:203.

Lewis SM and Verwilhen RL, editors. *Quality Assurance in Haematology.* London: Bailliere Tindal. 1988.

Lotspeich-Steininger CA, Stiene-Martin EA, and Koepke JA. *Clinical Hematology: Principles, Procedures, Correlations.* Philadelphia and New York: JB Lippincott Company. 1992.

National Committee for Clinical Laboratory Standards. *Internal Quality Control Testing: Principles and Definitions.* Approved Guideline. NCCLS Document C24-A. Villanova, PA. 1991.

National Committee for Clinical Laboratory Standards. *Method Comparison and Bias Estimation Using Patient Samples.* Tentative Guideline. NCCLS Document EP9-T. Villanova, PA. 1993.

National Committee for Clinical Laboratory Standards. *Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers.* Proposed Standard. NCCLS Document H26-P. Villanova, PA. 1989.

National Committee for Clinical Laboratory Standards. *Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture—Third Edition.* Approved Standard. NCCLS Document H3-A3. Villanova, PA. 1991.

National Committee for Clinical Laboratory Standards. *Procedure for the Collection of Diagnostic Blood Specimens by Skin Puncture—Third Edition.* Approved Standard. NCCLS Document H4-A3. Villanova, PA. 1991.

National Committee for Clinical Laboratory Standards. *Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods.* Approved Guideline. NCCLS Document H20-A. Villanova, PA. 1992.

Powers LW. *Diagnostic Hematology: Clinical and Technical Principles.* St. Louis: The CV Mosby Company. 1989.

Roberts B, editor, on behalf of the British Committee for Standards in Haematology. *Standard Haematology Practice.* Boston: Blackwell Scientific Publications. 1991.

Theml H. *Pocket Atlas of Hematology*. New York: Thieme. 1985.

Webster's Ninth New Collegiate Dictionary. Springfield, Mass: Merriam-Webster Inc. 1990.

NOTES

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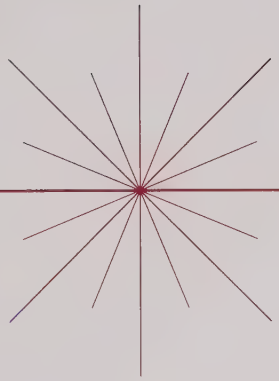

Revision Status and Log

Revision Status

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised and Added
Originally Issued	2/95	Not Applicable	Not Applicable

NOTES

Revision Log

Instructions: Use this log to provide a permanent record to verify that revised section(s) and/or page(s) have been added to this manual.

1. Record the document control number of the revised section in the first column. You will find the number in the footer. Make an entry for each section you receive and place in the manual.
2. Record the revision date, also found in the footer, in the second column.
3. Write your initials or signature in the fourth column to verify that you have placed the revised page(s) in the manual.
4. Record the date that you added the revised section to the manual in the fifth column.

Document Control Number	Revision Date	Software Version (if applicable)	Revision Incorporated by	Date Incorporated

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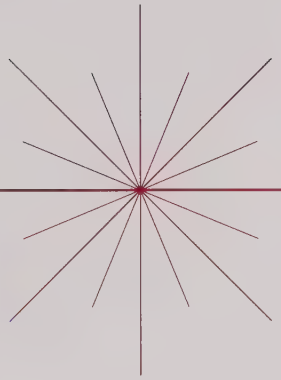

Glossary

Glossary

absolute count — The concentration of a cell type, expressed as a number per unit volume of whole blood.

absorbance — Use, by an atom or a molecule, of light energy to raise electrons from their ground state orbitals to orbitals at higher energy levels.

accuracy — The measurement of agreement between the estimate of a value (the result generated by the method) and the "true" value. Accuracy has no numerical value; it is measured as the amount of (or degree of) inaccuracy [ICSH]. The degree of agreement between a measured value and the expected value of a sample.

agglutination — The action of cells or particles clumping or sticking together.

agglutinin — An antibody present in the plasma or suspending media that reacts with an agglutinogen to cause agglutination or aggregation.

aggregation — *See* agglutination.

alarm — A warning indicator output in the form of a displayed message. Intended to alert the operator to an abnormal system condition.

alerted results — Measurement data that are flagged to indicate the suspected presence of one or more abnormal cell populations, interfering substances or conditions, or instrument faults.

algorithm — A step-by-step procedure for solving a problem; often coded into computer software.

anisocytosis — A variation in red blood cell size.

anticoagulant — A substance that interferes with the normal clot-forming mechanism of blood.

aperture — An opening with a specific diameter and length that exhibits a known, fixed resistance to electrical current when immersed in a specific conductive medium. Acts as a sensing zone for impedance measurements.

autoagglutination — Nonspecific clumping together of cells due to physical/chemical factors.

automated hematology analyzer — An instrument that accepts whole blood directly for analysis and outputs results upon completion.

auto-calibration	A selectable activity on the CELL-DYN 1700 system that steps the operator through the calibration process and automatically calculates a calibration factor for each parameter being calibrated.
auto-clean	A selectable activity available on the CELL-DYN 1700 that is used to automatically clean the analyzer flow system.
band cell (band)	A granulocyte development state prior to segmentation. Usually present in circulation in low concentrations. Indicates a "left shift" when present in greater concentrations.
basophil	A granulocytic white blood cell usually present in circulation in extremely low concentrations. Functions include allergy, inflammation, and histamine release.
basophilia	An increase in the absolute concentration of basophils in circulation. Often seen in chronic myelogenous leukemia.
bias	A systematic factor resulting in inaccuracy. A measure of inaccuracy, or systematic error under specified conditions of analysis.
bias, analytical	The numerical difference between the mean of a set of replicate measurements and the true value [NCCLS].
blast	The first stage of a blood cell lineage which can be morphologically identified on a stained smear. Normally present in bone marrow, but not in circulation.
blood, whole	Homogenous mixture of blood, not allowed to be separated into cellular and liquid components.
calibration	The determination of a bias conversion factor for an analytical process under specified conditions in order to obtain accurate measurement results. The accuracy over the operating range must be established by appropriate reference methods, reference materials, and/or calibrators [ICSH].
calibration factor	A multiplier obtained during calibration that can be applied to raw data in order to obtain accurate results.
calibrator	A material of known characteristics used in conjunction with a calibration procedure to adjust a measurement procedure. The material must be traceable to a national or international reference preparation or material.

carboxyhemoglobin — A fairly stable union of carbon monoxide with hemoglobin; its formation prevents the normal transfer of carbon dioxide and oxygen during the normal circulation of blood; increasing levels result in varying degrees of asphyxiation, including death.

carryover — Significant interference from a previous specimen on the current specimen results.

CBC — Acronym for complete blood count. Includes WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT.

cell — A small, usually microscopic mass of protoplasm bound externally by a semipermeable membrane. Cells usually contain one or more nuclei and various nonliving products.

coagulation — The process by which blood thickens into a coherent, viscous mass.

coefficient of variation (cv) — A statistical parameter used to describe population heterogeneity. The expression of the standard deviation as a percentage of the mean.

coincidence correction — A statistical analysis process that adjusts the count for coincidence loss. In the CELL-DYN 1700, analog circuitry automatically applies the correction.

coincidence loss — A decreased count that occurs when two or more cells simultaneously pass through the aperture. The resulting interruption in current flow is sensed as a single pulse, causing loss of one or more cells from the count.

coincidence passage — The simultaneous travel of two or more cells through the aperture.

cold agglutinin — A substance in blood that, at low temperatures, aggregates compatible and incompatible red blood cells. Also called cold hemagglutinin.

control (control material, quality control material) — A substance used in routine practice for checking the concurrent performance of an analytical process or instrument. These materials must be similar in properties to and be analyzed in the same manner as patient specimens. Control materials may or may not have preassigned values [ICSH, NCCLS].

corpuscle — A living red or white blood cell not aggregated into continuous tissues.

correlation coefficient	The degree to which two variables are related, expressed as a value on a scale from -1.0 to 1.0, with 1.0 as a perfect positive correlation and -1.0 as a perfect negative correlation. A 0.0 value indicates no correlation between the variables.
cryofibrinogen, cryoglobulin	Any of several proteins similar to gamma globulins that crystallize when cooled and redissolve when warm.
data log	A file or repository that automatically accepts and stores all time-stamped cycle data.
differential white blood cell count	The process of classifying white blood cells present in a specimen of whole blood into five or more distinct subpopulations and outputting a result for each identified subset as a percentage and as an absolute value.
dilution ratio	A factor by which a specimen is diluted before being measured. Specimens are diluted in different ratios to provide a cell concentration suitable for measurement.
drift	Variation or change in a system over time which significantly affects performance.
EDTA	An acronym for ethylene diamine tetra acetate. An anticoagulant that binds calcium. It is the most commonly used anticoagulant for hematology because it maintains cell morphology closest to the in vivo state for analysis. May be liquid (K_3 or K_2) or powder (Na_2).
eosinophil	A mature granulocytic white blood cell normally present in circulation in low concentrations. Functions include host defense to certain parasites, allergy, inflammation, and phagocytosis.
eosinophilia	An increase in the absolute concentration of eosinophils in circulation.
error, random	Variation, with no distinct pattern, between successive analysis process data. Often assumed to be a normal (Gaussian) distribution around a mean.
error, systematic	Directional or patterned variation between values obtained and the values expected.

erythrocyte — A small, biconcave, circular disk approximately 7.5 µm in diameter, with no nuclei. Erythrocytes are mature cells present in greater concentrations than others in circulating blood (averaging 5 million cells per microliter of whole blood).

expiration date — The date assigned by the manufacturer after which a product is no longer acceptable for use. Reagents, controls, and calibrators have expiration dates affixed during the manufacturing process.

extended count — An extension of measurement time which automatically occurs whenever a detected concentration for a particular cell type is not reached during the normal measurement time.

fault — Implying a failure. A detected condition that has failed internal acceptance criteria. Fault indicators activate to alert the operator.

femtoliter (fL) — A unit of measure to express the volume of blood cells.

fibrin — The end product of coagulation, derived from plasma protein, fibrinogen, by the action of thrombin.

fibrinogen — The major plasma protein that is the substrate for thrombin action to form fibrin; coagulation factor I.

flag — Written or displayed output intended to signal or attract attention. Flags are output by the computer to alert the operator to data abnormalities that were detected during the analysis process, or to analyzer situations that occurred during specimen processing. Operator review and/or corrective action usually required.

flag, dispersional data alert — A displayed or printed indication that signals the presence of cell concentrations and/or values that fall outside the operator-selectable range.

flag, suspect parameter — A displayed or printed indication that signals the presence of a substance or condition that may affect the accuracy of a parameter's measurement.

flag, suspect population — A displayed or printed indication that signals the suspected presence of red blood cell abnormalities, such as Anisocytosis, and/or the suspected presence of abnormal white blood cells, for example, bands, immature granulocytes, blasts, and variant lymphocytes.

gain — The amount of amplification generated by an amplifier, presented as a ratio of the output to input signals.

gaussian distribution	A statistical term describing distribution within a population; assumes a symmetrical distribution with a single peak.
GRAN	The identifier for the granulocyte result output as an absolute concentration per unit volume of whole blood: # x 10^9/L or # x 10^3/μL.
granulocyte	A mature white blood cell that contains prominent cytoplasmic granules: neutrophils, eosinophils, basophils, and mast cells. Granulocytes possess irregular nuclei.
granulocytosis	An increase in the absolute concentration of granulocytes in circulation.
HCT	The identifier for the hematocrit result output as a volume percentage or as a ratio.
hematocrit	The ratio of the red blood cell volume to whole blood volume, expressed as a percentage (vol %).
hemoglobin	An intraerythrocytic, iron-containing protein that transports oxygen. It functions as a tetramer of four globulin chains, each containing a heme moiety.
hemolysis	Destruction of red blood cells with liberation of hemoglobin.
heparin	An anticoagulant that combines with and enhances anti-thrombin III to prevent blood clotting. Not recommended for specimens being run on hematology analyzers.
HGB	The identifier for the hemoglobin result output as the concentration mass (# g/dL, # g/L) or moles (# mmol/L) of hemoglobin per unit volume of whole blood. On the CELL-DYN 1700, the output unit is operator selectable.
histogram	Graphical presentation of the size frequency distribution of measured blood cells. Volumetric size is represented on the x-axis and the relative cell concentration is represented on the y-axis.
hyperbilirubinemia	An abnormally large amount of bilirubin in the circulating blood, resulting in clinically apparent icterus or jaundice when the concentration is sufficient.
hyperglycemia	An abnormally high concentration of glucose in the circulating blood, especially with reference to a fasting level.

hypochromic (hypochromia, hypochromasia)	Decreased hemoglobin content in the red blood cells. Low MCH and decreased pigment on a stained smear.
ICSH	An acronym for the International Committee for Standardization in Haematology.
ID, operator	An alphanumeric code that identifies the current operator of the system.
ID, specimen	An alphanumeric code that identifies a particular specimen. It can be entered automatically , or by activating the auto-increment feature. It also can be entered manually before running the specimen.
impedance (electrical resistivity) method	A process that detects and sizes nonconductive cells suspended in a conductive medium as they are drawn into and through the aperture (sensing zone). Each cell displaces its own volume of conducting liquid and creates a resistance to current flow that is directly proportional to its own volume. Each cell's detected physical properties are converted to equivalent electrical signals.
imprecision	The variation in the results of a set of replicates or duplicate measurements, expressed as a standard deviation or coefficient of variation. See also *precision*.
inaccuracy	The numerical difference between the mean of a set of replicate measurements and the expected value. The difference (positive or negative) may be expressed in the units in which the quantity is measured, or as a percentage of the expected value [ICSH].
indices	A group of calculated values for red blood cell properties: mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).
interfering substances/ condition (spurious results)	A specimen component that affects the accuracy of a parameter's measurement.
in vitro	A term describing diagnostic tests that analyze a patient specimen from a test tube or other controlled environment (literally, "in glass").
in vivo	Within the living body.

leukocyte — A cellular constituent of circulating blood that is present in the lowest concentration, averaging 7,000/µL of whole blood. They are initially differentiated based on nuclear properties as polynuclear and mononuclear. They may be further differentiated based on the presence of granules in their cytoplasm as granulocytes, lymphocytes, and monocytes. Leukocytes function to guard tissues against invasion by foreign organisms or chemicals.

Levey-Jennings plot — A graphical presentation of data points from multiple runs for a single parameter, useful for trend analysis in quality control. The Y-axis represents the mean, lower, and upper limits, while the X-axis represents the runs.

linearity — The ability of an analytical process to provide measurements proportional to an analyte measured over a defined range of concentrations or counts [NCCLS].

lipemia — A condition in which there is a higher than normal concentration of lipids in the blood, seen as a milky-looking plasma; can interfere with hematology results obtained optically.

LIS — An acronym for laboratory information system.

LRI — An acronym for lower region interference. A displayed or printed indication of a detected abnormality specific to the lower platelet size region requiring further review.

LYM — The identifier for the lymphocyte result output as an absolute concentration per unit volume of whole blood: # x 10^9/L or # x 10^3/µL.

lymphocyte — A small, mature mononuclear white blood cell that is present in circulation in relatively high concentrations (20%-50%). It has a round or slightly indented nucleus and no granules evident in the cytoplasm.

lymphocytosis — An absolute increase in the concentration of lymphocytes in circulation.

lymphopenia (lymphopenic) — An absolute decrease in the concentration of lymphocytes in circulation.

lyse — Alteration or destruction of a cell.

lysing or lytic agent	A reagent that chemically reacts with the cell membrane, causing alteration or destruction of the cell.
lysis	The process of alteration or destruction of cells.
macrocytic (giant) PLT	A large platelet.
macrocytic RBC (macrocyte)	A large red blood cell in circulation.
macrocytosis	An overall increase in large red blood cells in circulation. Associated with deficiencies in vitamin B12 and folate, and with certain therapies.
MCH (mean corpuscular hemoglobin)	An acronym for mean corpuscular hemoglobin. The identifier for the mean corpuscular hemoglobin result output as the hemoglobin content of the average red blood cell, expressed in picograms.
MCHC (mean corpuscular hemoglobin concentration)	An acronym for mean corpuscular hemoglobin concentration. The identifier for the mean corpuscular hemoglobin concentration result output as the concentration of the hemoglobin in the red blood cell mass expressed as a percentage (%).
MCV (mean corpuscular volume)	An acronym for mean corpuscular volume. The identifier for the mean corpuscular volume result output as the volume of the average red blood cell expressed in femtoliters.
metamyelocyte	A cell present in the bone marrow that gives rise to a granulocyte and is not normally present in circulation. The maturation phase between myelocyte and band. Considered an immature granulocyte (IG).
metering, volumetric	A method of determining the exact volume of a prepared sample that has been measured. In the CELL-DYN 1700, this is done with a syringe that is controlled by a stepper motor.
method, reference	A clearly and exactly described technique for a particular determination which, in the opinion of a competent authority, provides a sufficiently accurate and precise determination for it to be used to assess the validity of other laboratory methods. The accuracy of the reference method must be established by comparison with a definitive method, when one exists. The accuracy and degree of imprecision must be stated [NCCLS].
mircocytic PLT	A small platelet in circulation.

microcytic RBC (microcyte)	A small red blood cell in circulation.
microcytosis	The overall increase in small red blood cells in circulation. May be associated with iron deficiency, hereditary hemoglobin disorders, sideroblastic anemias, chronic disorders, and renal failure.
microhematocrit method	The determination of the packed cell volume (PCV) of red blood cells using a small quantity of whole blood, a capillary tube, and a high-speed centrifuge.
monocyte	A large, mature mononuclear white blood cell that is normally present in circulation in low concentrations. The immature form of macrophage.
monocytosis	An absolute increase in the concentration of monocytes in circulation.
moving average file	A data repository that automatically accepts and stores time-stamped, batch means as they are calculated for operator review either in a summary log or Levey-Jennings plot (trend analysis) report format.
moving average program	A statistical routine that monitors system performance as specimens are run.
MPV	An acronym for mean platelet volume. The identifier for the mean platelet volume result output as the average volume of a platelet expressed in femtoliters. The MPV varies inversely with platelet count.
myelocyte	A cell present in bone marrow that gives rise to a granulocyte and is not normally present in circulation. Considered an immature granulocyte.
NCCLS	An acronym for the National Committee for Clinical Laboratory Standards.
neutropenia (neutropenic)	An absolute decrease in the concentration of neutrophils in circulation.
neutrophil	A mature granulocytic white blood cell present in circulation in high concentrations. Characterized by a segmented nucleus made up of two to eight lobes, and a pinkish to beige cytoplasm containing faint granules.

neutrophilia	An absolute increase in the concentration of neutrophils in circulation.
nucleated red blood cell	A nucleated cell present in the bone marrow that gives rise to a red blood cell and is not normally present in circulation.
nucleus	A cellular organelle that is essential to cell functions such as reproduction and protein synthesis.
orifice	*See* aperture.
packed cell volume	The measure of the ratio of the volume occupied by the red blood cells to the volume of whole blood.
parameter	An identifier and quantity that describe a statistical population. In hematology, the individual cell characteristic being tested, the identifier and result output for that characteristic. For example, red blood cell count (RBC) or hemoglobin concentration (HGB).
PCT	The identifier for the Plateletcrit result output as a ratio: # mL/L.
PDW	The acronym for platelet distribution width. The identifier for the platelet distribution width result output as the coefficient of variation of the platelet size distribution. Varies inversely with MPV.
plasma	The fluid part of whole blood as distinguished from suspended cells.
platelet	*See* thrombocyte.
plateletcrit	The ratio of the platelet volume to whole blood volume expressed as a ratio (mL/L).
PLT	An acronym for platelet or platelet count. The identifier for the platelet result output as an absolute concentration per unit volume of whole blood: # x 10^9/L or # x 10^3/µL.
poikilocytosis	A morphological condition characterized by variable-shaped red blood cells.
polychromatic (polychromasia, polychromatophilia)	A morphological abnormality characterized by the presence of an increased number of red blood cells that have basophilic (blue-gray) tint on Wright-stained smears, indicating the presence of cytoplasmic RNA.
polycythemia	An increased concentration of red blood cells in circulation.

polymorphonuclear (PMN or Poly) — A white blood cell that has a segmented nucleus and contains granules, for example, a mature granulocyte such as a neutrophil or eosinophil.

precision — The degree of agreement in the results of a set of replicate or duplicate measurements. Precision has no absolute numerical value. It is expressed as imprecision, which is a standard deviation or coefficient of variation. See also *imprecision*.

promyelocyte — A cell present in the bone marrow that gives rise to a granulocyte and is not normally present in circulation. Considered an immature granulocyte.

QA — An acronym for quality assurance.

QC — An acronym for quality control.

QC file — A repository that stores data automatically each time a control specimen is run, for review and output in a summary or Levey-Jennings plot format. The mean, SD, and CV calculations are automatically updated each time data are received.

quality control (external) — A system of retrospectively and objectively comparing results from different laboratories by means of surveys organized by an external agency. The main objective is to establish between-laboratory and between-instrument comparability, if possible, with a reference standard where one exists [ICSH].

quality control (internal) — A set of procedures undertaken by the staff of the laboratory for continual evaluation of the reliability of its work. The procedures determine whether the test results are reliable enough to be released to the requesting clinicians. These procedures should include tests on control material and statistical analysis of patient data [ICSH].

range — A measure of the dispersion of values. The difference between the largest and the smallest of a group of measurements.

RBC — An acronym for red blood cell or red blood cell count. The identifier for the red blood cell result output as an absolute concentration per unit volume of whole blood: # x 10^{12}/L or # x 10^{6}/µL.

RDW — An acronym for red cell size distribution width. The identifier for red cell size distribution width result output as the coefficient of variation of the red cell size distribution: # CV. An indicator of Anisocytosis.

reagent — A substance selected for its chemical or biological activity for diluting, and in some cases, altering the cells in a whole blood specimen, in preparation for measurement by the Analyzer.

red blood cell — *See* erythrocyte.

reference interval — The normal range established by a testing site. Site variables, such as, the test method, geographical location, interfering substances, age, and sex will cause slight variations in reference intervals obtained by different sites.

The normal range is determined by testing specimens collected from between 100 and 300 normal healthy individuals and calculating a mean and ±2SD. Test results for 95% of the normal population will be within this established range.

reliability — The extent to which an experiment, test, or measuring procedure yields the same results on repeated trials.

reproducibility — The ability of a procedure to obtain results during repeat analyses which closely imitate, within specified limits, the results obtained initially.

sample — A part or a unit taken at random from a large whole, and so presumed to be typical of its qualities. A representative part (aliquot) obtained from the collected whole blood specimen, which is diluted and analyzed. Sometimes used synonymously with specimen.

sampling mode — The means used by the Analyzer to aspirate a specimen (in the CELL-DYN 1700, can be either Open or Closed).

sensitivity, analytical — The minimal detectable value. The least quantity that can be discriminated from the background noise [NCCLS].

sensitivity, clinical — A test's ability to recognize individuals with the suspected illness for which the test is being run. A method's ability to obtain positive results in correlation with positive results obtained by a reference method. The percentage or proportion of patients with a well defined clinical disorder who have test values that exceed the decision limit [NCCLS].

sequence number — A unique cycle identifier that is automatically assigned to data (results) produced during that cycle. Primary means used by the computer to track Data Log entries.

setup data	Operator-selectable criteria or entries that customize the Analyzer operation and data output formats.
shift	An abrupt change in the result.
slope	Represents a proportional systematic error. If both methods are in agreement, the slope will be 1.0. A slope of 1.0 ± 0.05 is considered acceptable agreement.
specificity, analytical	Freedom from measurement interference. The ability of an analytical method to determine only the component being measured [NCCLS].
specificity, clinical	A test's ability to recognize individuals without the suspected illness for which the test is being run. A method's ability to obtain negative results in correlation with negative results obtained by a reference method. The percentage or proportion of patients who do not have a well defined clinical disorder who have test values that do not exceed the decision limit [NCCLS].
specimen	Collected whole blood that is presented to the Analyzer for sampling. Sometimes used synonymously with sample.
stability	The ability of a specimen, reagent, or control to maintain a constant concentration of the analyte. May also refer to the ability of an analytical system to avoid drift.
standard deviation (SD)	A measure of the dispersion of a group of values around a mean. The square root of the variance expressed in the same units as the measurements themselves.
standard deviation index (SDI)	A measurement of both the systematic and random error, denoting how many standard deviations a particular number is from the mean. Used in external quality control programs to relate the performance of a laboratory with that of other participating laboratories. A perfect SDI is 0, and it should always be less than 1.0.
status box	The location on the CELL-DYN 1700 screen where messages requiring operator attention are displayed.
syringe	A device that consists of a hollow barrel fitted with a plunger used to deliver or inject a precise volume of diluted sample.
thrombocyte	Circulating cytoplasmic fragments of the megakaryocytes present in moderate concentrations, averaging about 250,000/µL of whole blood. Contain no nuclei and have some granules.

trend — A situation in which a result moves in the same direction for several consecutive runs.

unit of measure — A determinate quantity adopted as a standard of measurement. Associated with a numerical result for a measured quantity or property.

uremia — The abnormal presence of urinary constituents in the blood.

URI — An acronym for upper region interference. A displayed or printed indication of a detected abnormality specific to the upper platelet size region requiring further review. This interference flag usually results from the presence of large platelets or small red blood cells.

verification — A protocol or procedure followed to test the performance of a system or component to ensure that it meets stated specifications.

WBC — An acronym for white blood cell or white blood cell count. The identifier for white blood cell result output as an absolute concentration per unit volume of whole blood: # x 10^9/L or # x 10^3/µL.

Westgard rules — A multirule system described by James Westgard for identifying out-of-control QC results, based on control procedures initially described by Walter Shewhart and later by Levey and Jennings. Uses a set of statistical rules to assess and validate QC data.

white blood cell — *See* leukocyte.

X-B (moving average program) — An identifier for the moving average program developed by Dr. Bull. A statistical program that monitors system performance as specimens are run. Any result for each monitored parameter, such as MCV, MCH, and MCHC which meets acceptance criteria is automatically included in a current batch.

Y-intercept — A representation of constant systematic error. The interpretation depends on the substance being measured. A perfect correlation of two methods will give a Y-intercept value of 0. The lower the number, the better the correlation.

NOTES

References

Barnett RN. *Clinical Laboratory Statistics.* Boston: Little, Brown and Company. 1979.

Brown BA. *Hematology: Principles and Procedures.* Philadelphia: Lea & Febiger. 1993.

Campbell MJ and Machin D. *Medical Statistics: A Common Sense Approach.* New York: John Wiley & Son. 1993.

Hillman RS and Finch CA. *Red Cell Manual.* Philadelphia: FA Davis Company 1992.

International Committee for Standardization in Hematology (ICSH). Protocol for Evaluation of Automated Blood Cell Counters. *Clinical and Laboratory Hematology.* 1988; 10:203.

Lewis SM and Verwilhen RL. *Quality Assurance in Haematology.* London: Bailliere Tindal. 1988.

Lotspeich-Steininger CA, Stiene-Martin EA, and Koepke JA. *Clinical Hematology: Principles, Procedures, Correlations.* Philadelphia and New York: JB Lippincott Company. 1992.

National Committee for Clinical Laboratory Standards. *Internal Quality Control Testing: Principles and Definitions.* Approved Guideline. NCCLS Document C24-A. Villanova, PA. 1991.

National Committee for Clinical Laboratory Standards. *Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers.* Proposed Standard. NCCLS Document H26-P. Villanova, PA. 1989.

National Committee for Clinical Laboratory Standards. *Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods.* Approved Guideline. NCCLS Document H20-A. Villanova, PA. 1992.

Powers LW. *Diagnostic Hematology: Clinical and Technical Principles.* St. Louis: The CV Mosby Company. 1989.

Roberts B, editor, on behalf of the British Committee for Standards in Haematology. *Standard Haematology Practice.* Boston: Blackwell Scientific Publications. 1991.

Webster's Ninth New Collegiate Dictionary. Springfield, Mass: Merriam-Webster Inc. 1990.

NOTES

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CELL-DYN® 1700 SYSTEM

Appendices

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Appendix A — Parts and Accessories

To place an order for these products, dial our toll-free Customer Service Network at 1 (800) 323-9100.

If you require technical assistance for your CELL-DYN System, contact the Customer Support Center at 1 (800) CELL DYN (235-5396).

CELL-DYN Equipment, Parts, and Accessories

Abbott List Number/Part Number	Description of Part	Configuration
03H54-01	Accessory Kit (NOTE: For a list of items in the Kit, see the Accessory Kit Table on the following page.)	1
03H58-01	Operations Manual	1
03H55-01	CELL-DYN 1700 Pedestal	1
20821-01	Printer (120V)	1
20822-01	Printer (220V)	1
03H56-01	Keyboard	1
93009-01	Peristaltic Pump Tubing (Lg)	1
92274-01	Aperture Plate WBC	100 µM
92264-01	Aperture Plate RBC	60 µM
N/A	Check Valve	1
28561-01	Lyse Syringe	2.5 mL
28541-01	Dilute Syringe	10 mL
28514-01	Sample Syringe	100 µL
21704-01	Waste Dummy Plug	1
93164-01	Sample Probe	1
54305-01	Aperture Brush	1
92178-01	Lyse Line Inlet Assy	1
92159-01	Detergent Line Inlet Assy	1
92163-01	Diluent Line Inlet Assy	1
92161-01	Waste Line Assy	1
91072-01	Reagent Line Kit	4 lines
20005-01	Printer Cable	1
93501-01	Power Cord	1

Abbott List Number/Part Number	Description of Part	Configuration
99605-01	CELL-DYN Counting Cups (Disposable Sample Vials)	500
04H03-01	Interface Specifications	1

CELL-DYN Accessory Kit

Abbott List Number/Part Number	Description of Part	Configuration
03H58-01	Operations Manual	1
1403204	Keyboard Cover	1
N/A	Fuse, SB 2.5 amps 220/240 V	2
N/A	Fuse, SB 5.0 amps 110/120 V	2
N/A	Printer Paper 9.5" x 11"	1
93501-01	Power Cord	1
N/A	Allen Wrench 3/32"	1
N/A	Allen Wrench 7/64"	1
54305-01	Aperture Brush	1
91072-01	Reagent Line Kit	1
N/A	Printer Stand	1
20005-01	Printer Cable	1
93009-01	Peristaltic Pump Tubing	4 ea

CELL-DYN Reagents

Abbott List Number	Description of Part	Configuration
99420-01	Lyse	3.8 liter cube
99435-01	Lyse	1 x 960 mL bottle
99320-01	Detergent, Diff-Screen	20 liter cube
99326-01	Detergent, Diff-Screen	4 x 3.8 liter bottles
98329-01	Detergent, Diff-Screen	1 x 3.8 liter bottle
99220-01	Isotonic Diluent, Diff-Screen	20 liter cube
99226-01	Isotonic Diluent, Diff-Screen	4 x 3.8 liter bottles
99229-01	Isotonic Diluent, Diff-Screen	1 x 3.8 liter bottle

CELL-DYN Controls and Calibrators

Abbott List Number	Description of Part	Configuration
99109-01	CELL-DYN 16 Tri-Level Control (Vial)	12 x 2.5 mL
99131-01	CELL-DYN 16 Tri-Level Control (VACUTAINER®)	12 x 3.0 mL
99110-01	CELL-DYN 16 Calibrator	2 x 2.5 mL
93111-01	CELL-DYN 3000 Control (Vial)	12 x 2.5 mL
99129-01	CELL-DYN 3000 Control (VACUTAINER®)	12 x 3.0 mL
99120-01	CELL-DYN 3000 Calibrator	2 x 2.5 mL

CELL-DYN Consumables

Abbott List Number	Description of Part	Configuration
99644-01	Enzymatic Cleaner Concentrate	2 x 50 mL
99610-01	Micropipettes (40-µL)	100 pkg.
99620-01	Printout Tickets	1000 pkg.
30005-01	Graphics Paper	3000 sheets/pkg.
13401-01	Ribbon OKIDATA® 320	1
99660-01	DYN-A-WIPE™ lint-free pads	125 pkg.
98661-01	DYN-A-WIPE™ lint-free pads	40 pkg./case

NOTES

Appendix B — Reference Tables

Table B-1: Potential Causes of Spurious Results with Automated Cell Counters

Parameter	Causes of Spurious Increase	Causes of Spurious Decrease
White Cell Count (WBC)	Cryoglobulin, cryofibrinogen Heparin Monoclonal proteins Nucleated red cells Platelets clumping Unlysed red cells	Clotting Smudge cells Uremia plus immunosuppressants
Red Cell Count (RBC)	Cryoglobulin, cryofibrinogen Giant platelets Elevated white cell count (> 30,000/μL)	Cold agglutinins Clotted specimen (microclot) Hemolysis (*in vitro*) Polycythemia (increased RBC coincidence) Microcytic red cells
Hemoglobin (HGB)	Carboxyhemoglobin (> 10%) Cryoglobulin, cryofibrinogen Hemolysis (*in vivo*) Elevated white cell count (>30,000/μL Hyperbilirubinemia, severe Lipemia Abnormal plasma proteins	Clotted specimen (microclot)
Hematocrit (Packed Cell Volume – Manual Method)	Hyponatremia Plasma trapping	Excess EDTA Hemolysis (*in vitro*) Hypernatremia
Mean Cell Volume	Autoagglutination High white cell count (>50,000/μL) Hyperglycemia Reduced red cell deformability Swollen red cells	Cryoglobulin, cryofibrinogen Giant platelets Hemolysis (*in vitro*) Microcytic red cells
Mean Cell Hemoglobin	High white cell count (> 50,000/μL) Spuriously high hemoglobin Spuriously low red cell count	Spuriously low hemoglobin Spuriously high red cell count
Mean Cell Hemoglobin Concentration	Autoagglutination Clotting Hemolysis (*in vivo* and *in vitro*) Spuriously high hemoglobin Spuriously low hematocrit	High white cell count (> 50,000/μL) Spuriously low hemoglobin Spuriously high red cell count
Platelets (PLT)	Cryoglobulin, cryofibrinogen Hemolysis (*in vivo and in vitro*) Microcytic red cells Red cell inclusions White cell fragments	Clotting Giant platelets Heparin Platelet clumping Platelet satellitosis

Source:

- Cornbleet J. Spurious Results from Automated Hematology Cell Counters. *Laboratory Medicine* 1983; 14:509-514.

Table B-2: Reference Intervals (Normal Values) for Automated Blood Counters

Parameter	Adult Male >18 Years	Adult Female >18 Years	Children at 1 Month	Children at 2 Years	Children at 10 Years
WBC (K/μL)	4.6 – 10.2	4.6 – 10.2	5.0 – 20.0	6.0 – 17.0	5.0 – 13.0
Lymphocytes (K/μL)	0.6 – 3.4	0.6 – 3.4	6.0^{mv}	6.3^{mv}	3.1^{mv}
Lymphocytes (%)	10 – 50	10 – 50	55^{mv}	60^{mv}	40^{mv}
Monocytes (K/μL)	0 – 0.9	0 – 0.9			
Monocytes (%)	0 – 12	0 – 12	6^{mv}	5^{mv}	4^{mv}
Eosinophils (K/μL)	0 – 0.7	0 – 0.7			
Eosinophils (%)	0 – 7	0 – 7	3^{mv}	2^{mv}	2^{mv}
Basophils (K/μL)	0 – 0.2	0 – 0.2			
Basophils (%)	0 – 2.5	0 – 2.5	0.5^{mv}	0.5^{mv}	0.5^{mv}
Neutrophils (K/μL)	2.0 – 6.9	2.0 – 6.9	3.8^{mv}	3.5^{mv}	4.4^{mv}
Neutrophils (%)	37 – 80	37 – 80	30^{mv}	30^{mv}	50^{mv}
RBC (M/μL)	4.69 – 6.13	4.04 – 5.48	3.9 – 5.9	3.8 – 5.4	3.8 – 5.4
Hemoglobin (g/dL)	14.1 – 18.1	12.2 – 16.2	15 – 18	11 – 13	12 – 15
Hematrocit (%)	43.5 – 53.7	37.7 – 47.9	44^{mv}	37^{mv}	39^{mv}
MCV (fL)	80 – 97	80 – 97	91^{mv}	78^{mv}	80^{mv}
MCH (pg)	27.0 – 31.2	27.0 – 31.2	33^{mv}	27^{mv}	25^{mv}
MCHC (g/dL)	31.8 – 35.4	31.8 – 35.4	35^{mv}	33^{mv}	34^{mv}
Platelets (K/μL)	142 – 424	142 – 424	277^{mv}	300^{mv}	250^{mv}
RDW (%)	11.6 – 14.8	11.6 – 14.8	N/A	N/A	N/A

SOURCES:

- Theml H. *Pocket Atlas of Hematology.* Stuttgart and New York: Thieme. 1985.
- Bessman J D. *Automated Blood Counts and Differentials.* Baltimore: Johns Hopkins University Press. 1986.

NOTES:

- ^{mv} denotes mean value.
- For adult black males and females, normal WBC is 2.9 – 7.7 K/μL.
- For adult black males and females, normal RBC, HGB, and HCT is 5% less.
- For children aged 6 months to 18 years, mean MCV value is approximately 75 + (0.8 x age in years).
- For newborns, MCV is 88 – 114 and RDW is 14.9 – 18.7.

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CELL-DYN® 1700 SYSTEM

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